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Is smoking associated with patient reported surgical-site infection after fusion surgery in the lumbar spine?

A Multicenter observational study based on data from the Norwegian registry for spine surgery.

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Master thesis/Class of 2013
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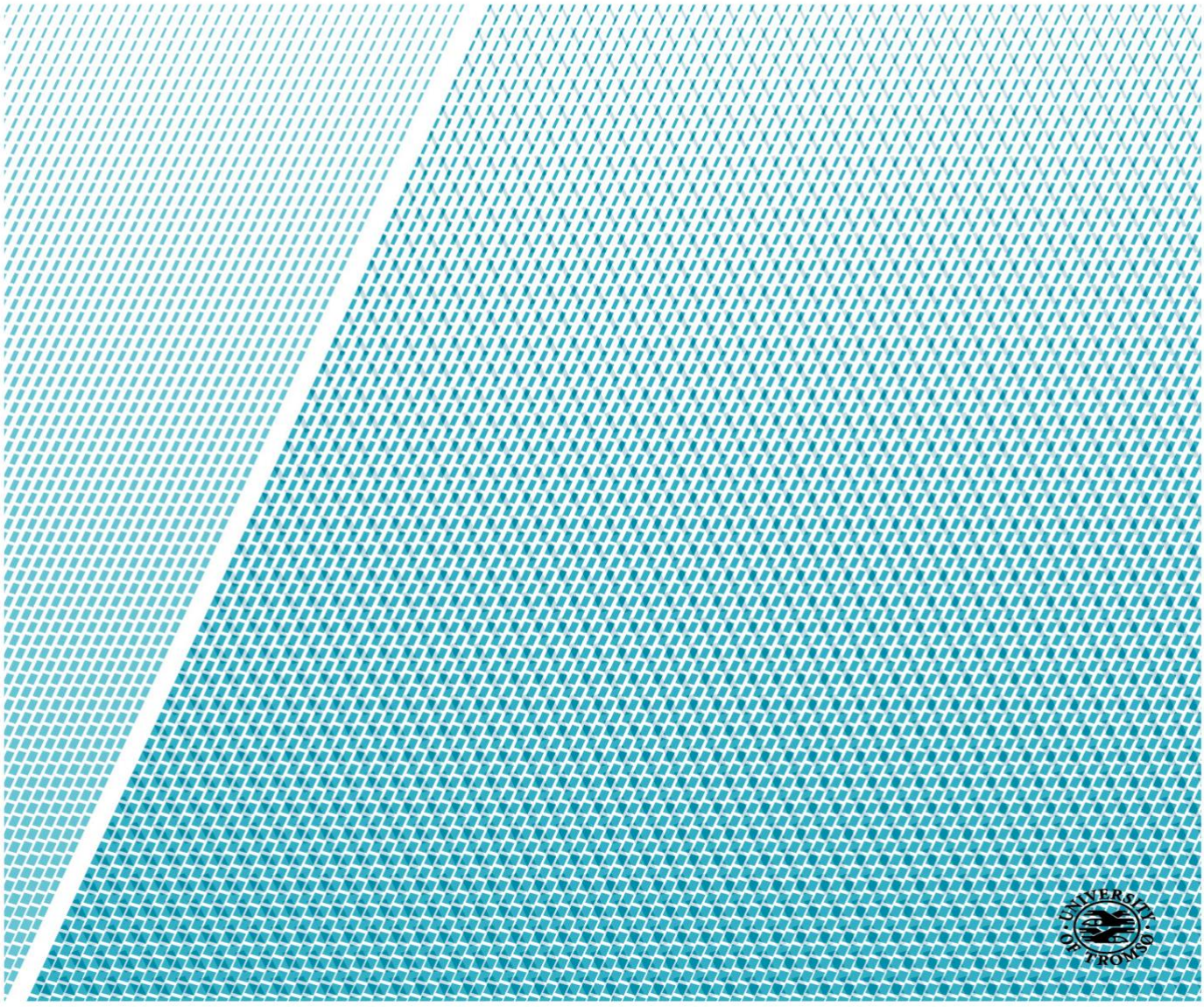

Preface

The purpose of this study was to identify risk factors for surgical site infection (SSI), and to investigate whether smoking is associated with an increased risk of SSI after spinal fusion of the lumbar spine. My curiosity for this topic started when I was working at the neurosurgical ward at the University hospital of Northern Norway, Tromsø. During the years I have been working there, I`ve met many patients who have been operated in the spine. Many of these patients were smokers. They were usually the easiest to mobilize postoperatively, because of their eager to go out and have a smoke. As I saw these patients that were recently operated and immediately went for a smoke after the operation, I was thinking about all the negative effects we've learned at medical school about tobacco smoke. The effects on peripheral circulation and microcirculation. The vasoconstrictive effect, and the deoxygenating effect of CO. This caught my interest to investigate whether smokers had a poorer outcome after lumbar spine surgery than non-smokers. Since SSI is the most common complication after spine surgery, this was the outcome measure chosen. The reason for selecting spinal fusion procedures, was to look at a group where the rates of SSI was thought to be higher. In our ward we collected data in the national spine registry (NORspine) on all patients operated in the spine. Thus, I decided to apply to the Ethical committee for medical research and got approval for this study. Hence the NORspine registry provided the data for this study. No funding was received.

I would like to express gratitude to my supervisor Professor Tore Solberg for his help with this study, his effort made a big difference in the work with this study. Despites a busy schedule with operations, surgery and volunteering abroad, he always made time for counseling. A lot of help was given with the statistics, professional inputs, correcting the paper etc. I could not have asked for a more competent supervisor on this paper than him, so thank you for all your help.

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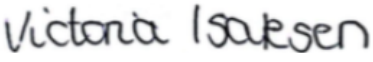

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Summary

Introduction: Surgical site infection (SSI) is one of the most common complications in patients undergoing spine surgery. Associations between smoking and SSI have been found in previous studies, but with ambiguous results. This study was designed to compare the postoperative rate of SSI among smokers and non-smokers after fusion surgery in the lumbar spine and evaluate risk factors for SSI.

Methods and materials: This observational study includes 2546 patients from the Norwegian Registry for Spine Surgery (NORspine), operated with arthrodesis (fusion) surgery for degenerative disorders of the lumbar spine. Data were collected prospectively from the date of operation (baseline) and at 3 months of follow-up. The primary outcome was surgical site infection, reported by the patient responding to a standardized questionnaire.

Ethics and dissemination: All participants of the NORspine registry have provided written informed consent. The regional committee for medical research in Northern Norway has approved this study.

Results: A total of 5.9% of the patients reported a SSI within three months after surgery. No association between smoking and SSI was found. ASA grade>2 (OR 2.07, 95%CI= 1.19-3.60, *p= 0.01*), lower age (OR 0.98, 95%CI=0.96-0.99 *p<0.01*) and days of hospital stay (OR 1.09, 95%CI=1.04-1.13, *p< 0.001*) were identified as independent risk factors for SSI. After stratifying the data on days of hospital stay (<10 days or >9 days), only ASA grade >2 were significant for both groups. For the ones that stayed less than 10 days at the hospital also lower age (OR= 0.98, 95%CI=0.96-0.94, *p=<0.01*) and previously operated in the back (1.74, 95%CI= 1.13-2.69, *p=0.01*) were independent risk factors. The risk of developing a SSI increased 1.7 fold with a hospital stay of 10 days or more.

Conclusions: The rate of postoperative SSI in this study is in line with previous literature. No increased risk of SSI between smokers and non-smokers were found.

Key-words, abbreviations, definition of terms

Key-words: spinal fusion, smoking, SSI, instrumentation

Abbreviations

PLF - Posterior lumbar fusion

PLIF - Posterior lumbar interbody fusion

ALIF - Anterior lumbar interbody fusion

TLIF - Transforaminal lumbar interbody fusion

SSI - Surgical site infection

ASA - American Society of Anesthesiologists (ASA)

HRQoL - Health related quality of life

CI - Confidence interval

OR - Odds ratio

Definition of terms

The term *surgical site infection* (SSI) used in this study means any infection (deep or superficial) occurring postoperatively at the surgical incision site.
Whereas the superficial SSI only affects the skin and the subcutaneous space, the deep SSI also involves the structures underneath the muscle fascia.

Spinal fusion is an operative procedure that unites two or more vertebral segments (vertebral bodies, pedicles and posterior elements) with a placement of a bone graft, with or without additional instrumentation. The aim is to restrict motion by an arthrodesis, and thereby relieve symptoms of segmental instability.

Instrumented fusion is the supplementation of hardware: plates, screws, rods, cages etc. This is used to support and improve bony fusion.

Spondylosis is degenerative changes that can affect the whole spine. It is a process that increases by age, and affects the intervertebral disc, bones, ligaments and facet joints. This can cause narrowing of the spinal canal and compression of neural structures, and can cause chronic leg and back pain (1).

Spondylolysis is a defect in a part of the vertebrae (fracture or separation), typically in the lumbar spine (isthmus of L5). This weakness might lead to the slipping of one vertebra in relation to another - a condition called *spondylolisthesis*, often interpreted as instability. This slip might contribute to the compression the spinal nerves in the nerve root foramina, and is associated to mechanical back pain. Spondylolisthesis without spondylolysis occurs among 15-20% of patients with spinal stenosis, other causes of spondylolisthesis may be bony dysplasia or trauma (2, 3).

ASA grade is a classification system to categorize a patient's general physical status. This grading is done by the anesthesiologist, and can help predicting perioperative risk and vulnerability of the patient (4).
It has six different classes:
ASA 1: Healthy
ASA 2: Mild systemic disease/smoker
ASA 3: Severe systemic disease that's not life threatening.
ASA 4: Severe systemic disease in a constant threat of life
ASA 5: Moribund patient that's expected to die within 24h
ASA 6: Brain-dead

Sepsis is defined as "the life-threatening organ dysfunction caused by a dysregulated host response to infection" (5), that can be lethal and has a high mortality.

Angiogenesis is the formation of new blood vessels.

Scoliosis is an abnormal lateral curvature of the spine. A structural alteration that rotates the

spine, making it look like a C or S shape. There are different causes for scoliosis: Congenital, degenerative, idiopathic etc. (6).

1 Introduction

1.1 Surgical site infection

Surgical site infection (SSI) is one of the most common complications following spine surgery (7). In a systematic review SSI varied from <1% to 10.9% among patients undergoing spinal surgery (8). More comprehensive surgical procedures increases the rates of SSI (9-11). For fusion surgery the rate of SSI has been reported to be 2.6-5.3% (12-15). SSI is a feared complication and is associated with increased mortality, morbidity and length of hospital stay (12, 16). Typically, a SSI is diagnosed by local inflammatory symptoms (pain, redness, swelling/pus formation, reduced wound healing and impaired function) and/or more severe systemic symptoms (lethargy, fever, sepsis). The deep wound infections might affect the implants and bony structures, including bone grafts, which might lead to non-fusion. The development of a postoperative SSI, contributes to disability and higher costs for patients and society (17, 18). Reasons for higher health care costs might be additional diagnostic work-up and treatment, longer hospital stay and sick leave. Some patients with SSI are re-operated which probably doubles the expenses (17).

Various risk factors have been linked to SSI, including: increasing age, diabetes, ASA score, previous spine surgery, obesity and smoking (8, 19-23). Knowledge about risk factors for SSI is essential for development of guidelines, aimed at preventing SSI among future patients.

1.2 Smoking

The health hazards of tobacco smoking have been well documented for decades (24). Smoking can cause diseases like: chronic lung disease, peripheral vascular disease, heart disease and cancer among others (25). Despite this knowledge and numerous health campaigns focusing on the dangers of smoking, it is still widespread. In Norway, the prevalence of daily smokers was 11% in 2017, which is a 50% reduction from 2007 when it was 22% (26). The World health

organization has named smoking to be one of the world's biggest public health threats, killing around 7 million people each year (27).

According to the surgical literature smoking increases postoperative complications (28). SSI have been evaluated in several studies, but it is still unclear whether there is an association between smoking and the risk of SSI. Several studies have found smoking to be an independent risk factor for SSI after spinal fusion (29-31). A meta-analysis from 2017 by Kong et al. comprised of 26 studies of both case-control and cohort studies found an increased risk of SSI among smokers compared to non-smokers after spine surgery (32). However, another meta-analysis of 12 case-control and cohort studies conducted by Fei et al in 2016, found no such association (33). The heterogeneity of these studies concerning study design, surgical location and technique, and patient characteristics, would be prone to selection bias. Moreover, most of the studies included were retrospective case-control studies. A recent study based on the NORspine data from 2017, evaluating risk factors for SSI after operated on for lumbar disc herniation without spinal fusion, found no association between smoking and SSI (34). A possible reason might be that this small surgical procedure generally has a lower complication rate. The number of SSI cases was only 40, which could lead to type II statistical errors. Patients operated with microsurgical decompression for lumbar spinal stenosis (LSS) in a study by Gulati et al showed that smokers experience less clinical improvement than non-smokers, but the complication rate was the same for the two groups (35).

The association between smoking and SSI is well documented in other surgical specialties, especially in the field of plastic surgery. Smoking restricts blood flow and decreases wound healing which may lead to tissue necrosis and SSI (36, 37). In a systematic review by Sørensen, all major studies from reconstructive and orthopedic surgery found increased rates of SSI among smokers (37).

1.2.1 Pathophysiology

Tobacco consist of a numerous different toxic components. The negative impact of smoking on wound healing is thought to be explained mainly by four substances: nicotine, carbon monoxide (CO), hydrocyanic acid (HCN) and nitrogen oxide (NO) (36). These substances mediates vasoconstriction, diminished angiogenesis, reduced O_2 transportation and inhibition of mitochondrial metabolism, causing hypoxia and tissue ischemia (36). Other negative effects like reduced inflammatory response and decreased epithelialization of wounds are key elements to why smoking is harmful when it comes to wound healing (36).

1.3 The degenerative spine

Degenerative changes of the lumbar spine known as spondylosis increases by age, and may lead to disc herniation, spinal stenosis and deformity (spondylolisthesis or scoliosis). Patients with these conditions often have chronic low back pain and/or radiating leg pain, with or without neurological deficits. The consequences for the patient are disability, reduced health related quality of life (HRQoL) as well as reduced working capability (38). Worldwide, lumbar-spine disorders account for higher costs resulting from disability and absenteeism from work than any other somatic disease category (38, 39). In a growing elderly population the surgical rate is likely to increase (40).

LSS is the most common indication for spine surgery in the elderly (40, 41). Properly selected patients have a better outcome with surgical treatment as compared to conservative treatment (42, 43). An operation aims to decompress the nerve- roots by widening the spinal canal. Decompression could potentially however destabilize the spine. For some of these patients additional spinal fusion with or without instrumentation has therefore been recommended to stabilize the spine and reduce postoperative back pain, especially in cases with concomitant degenerative or isthmic spondylolisthesis and/or scoliosis (44). More comprehensive surgery, e.g. the use of implants increases the risk of complications, such as SSI (9-11). In most cases the indication for surgery is relative to the subjective complaints of the patients.

In summary, different surgical procedures are used for similar conditions, ranging from microsurgery to more extensive “open techniques”, such as fusion surgery for instability.

Still, the results are variable, and the key to a successful outcome is careful patient selection prior to surgery and complication avoidance. Because risk is inherent in any surgical procedure, the decision to operate has to be based on a trade-off between possible benefits and risks. To the best of our knowledge there are no previous observational studies that has evaluated smoking and other risk factors for SSI, specifically for lumbar spinal fusion procedures. New knowledge about risk factors associated to adverse outcomes may facilitate prevention of SSI, guideline development and shared decision making between surgeons and patients.

1.4 Aim of the study

The aim of this study is to compare the rate of SSI within the first three months after surgery among smokers and non-smokers after fusion surgery (with or without instrumentation), and to identify independent risk factors associated to SSI.

2 Methods and materials

This multicenter observational study was conducted according to the checklist of Strengthening the Reporting of Observational studies in Epidemiology (STROBE criteria) (45).

2.1 Study population

The cohort comprises patients operated with spine surgery for degenerative changes in the back with spinal fusion (with or without instrumentation) at 23 different surgical units in Norway. The patients were included in the NORspine registry and were operated between 01.09.09 to 12.12.16. NORspine is a clinical registry for quality control and research. It is voluntary for the patient to be included in the registration, and the same treatment was offered to those who declined to participate in the registry cohort.

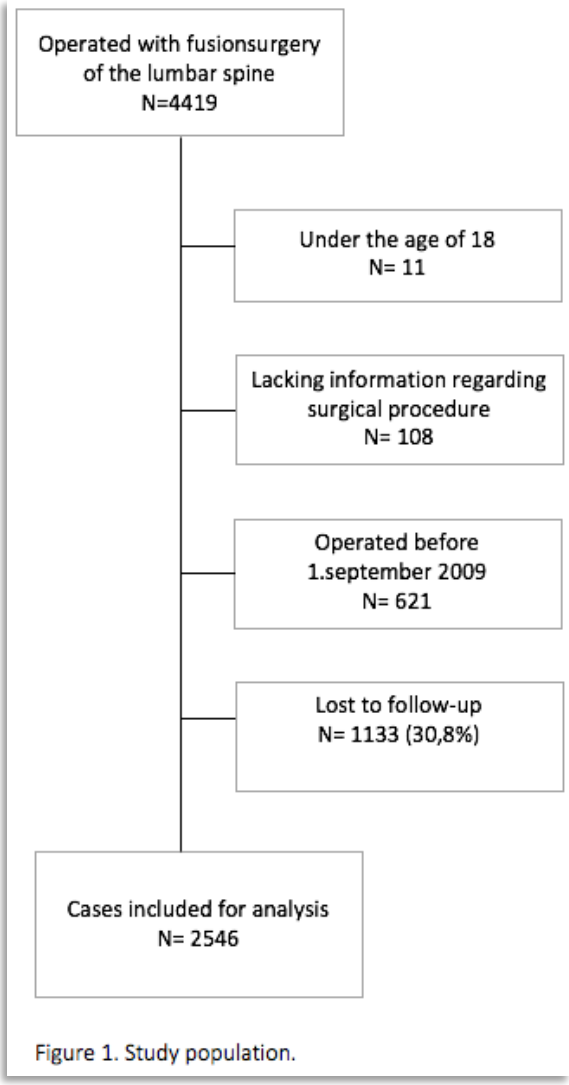

Figure 1. Study population.

From 02.01.07 to 12.12.16 the registry comprises a total of 32971 operations, of these 4419 underwent fusion-surgery. The remaining 28552 underwent other kinds of spine surgery and were not included. 108 patients were lacking information regarding the surgical procedure, which made it impossible to randomize them in a group: instrumented fusion or non-instrumented fusion, therefore the 108 was excluded. How the study population was created is illustrated in figure 1. In this study SSI are patient reported, we therefore excluded patients operated earlier than 1. September 2009, when SSI was reported by healthcare professionals. A total of 1133 out of 3679 (30.8%) participants did not respond to the questionnaire, and were lost to follow-up at 3 months. The remaining 2546 patients all underwent fusion surgery with or without instrumentation.

2.2 Inclusion and exclusion criteria

Inclusion

1. Included in the NORspine registry
2. Operated with spinal fusion in the lumbar spine - with or without instrumentation
3. Degenerative disorder

Exclusion

1. Spine surgery without fusion
2. Implantation not primarily aimed at providing fusion, i.e. disc prosthesis and interspinous distraction devices
3. Under the age of 18
4. Patients operated on before 1. September 2009

2.3 Data collection and registration

On admission for surgery (baseline) the patients completed self-administered questionnaires, which included questions about demographics and lifestyle issues. Information about marital status, mother tongue language, educational level, employment status, body mass index and tobacco smoking was available from the NORspine registry. During the hospital stay the surgeon recorded data concerning diagnosis and treatment, comorbidity including the *American Society of Anesthesiologists* (ASA) grade, duration of symptoms and image findings, using a standard registration form (both questionnaires are to be found in attachments). The follow-up did not involve any staff or health professionals at the treating hospitals. Questionnaires, identical to those completed at baseline, were distributed from the central registry office of the NORspine, completed at home by the patients and returned in pre- stamped envelopes. Patients who did not respond received one reminder with a new copy of the questionnaire.

2.4 Outcome measures

Outcome

• A SSI was reported by the patients, according to the self-administered questionnaire 3 months after the operation. The SSI was defined as superficial if the patient responds yes to question number 1 and as deep if yes to question number 2 below.

These questions were developed by the Swedish Spine Register (SWEspine) (34).

1. *Where you treated with antibiotics for a superficial infection at the surgical site during the first 4 weeks after the operation?*

2. *Have you or are you being treated with antibiotics for over 6 weeks for a deep surgical site infection?*

2.5 Surgical procedures

All patients were operated with fusion surgery. Patients operated with fusion surgery may be treated for spinal stenosis with or without degenerative spondylolisthesis, isthmic spondylolysis/spondylolisthesis, or lumbar disc degeneration and spondylosis without signs of nerve root compression. Both cases of instrumented and non-instrumented fusion were included. All types of instrumentation, i.e. standard posterior lumbar fusion with pedicle screws (PLF) anterior, posterior and transforaminal interbody fusion techniques (ALIF; PLIF and TLIF, respectively) were included.

2.6 Statistical analyses

Statistical analyses were performed using SPSS version 25.0 (SPSS, Inc., Chicago, IL). For statistical comparison within or between groups, statistical significance was defined as $p \leq 0.05$, with no adjustments for multiple comparisons. Continuous variables were analyzed using an unpaired two-tailed t-test for normally distributed data, and with the Mann–Whitney U-test if skewed. Normal distribution was checked using Kolmogorov-Smirnov test. Discrete variables

were compared by chi-square analysis. Risk factors recorded in the NORspine at baseline, judged to be clinically relevant were checked for co-linearity, and assessed in univariate analysis for associations to SSI or smoking habits. Those reaching a statistical significance ($p<0.1$) were checked for interactions and included in the final multivariate analyses (binary logistic regression) using surgical site infection (yes/no) as dependent and smoking (yes/no) as exposition variable. The following covariates were evaluated: age, sex, educational level, mother tongue language (Norwegian/other), obesity (Body mass index (BMI)> 30), comorbidity (diabetes, cancer, osteoporosis), ASA grade (>2), number of operated levels, previous low back surgery, duration of surgery, days of hospital stay, emergency surgery, the use of microscope and wound drain, prophylactic antibiotic treatment, use of instrumentation and type of hospital (private vs public).

2.7 Missing data

A patient was only excluded from a specific analysis if the actual data value was missing, but not from other analyses where necessary data was provided. Missing data analysis were performed, comparing baseline characteristics of respondents and non-respondents.

3 Results

3.1 Baseline characteristics

Characteristics of the study population is shown in table 1 and table 2.

The mean age (SD) was 57.4 (13.3) and a majority of the study population were females (58,6%). Almost 20% of the study population were smokers, which was higher than in the general population of Norway (26). The mean duration (SD) of surgery was 175.7 minutes (70.9), and mean length of hospital stay (SD) was 6.1 days (3.7). Of all patients, 2351 (92.3%) were operated in a public hospital.

All 2546 patients underwent fusion surgery with or without instrumentation, i.e : PLF was performed in 1205 (47.3%) of the cases, TLIF in 1086 (42.7%), ALIF in 168 (6.6%) and 87 (3.4%) underwent PLIF. A total of 2218 (87.1%) were instrumented fusions, whereas 328 (12.9%) were non-instrumented fusions. All of the surgical procedures with PLIF, TLIF and ALIF were instrumental.

Table 1. Characteristics of the study population at baseline, among patients who had surgical site infections (SSI) and no SSI

	All n= 2546		SSI n= 151		No SSI n= 2395		*P-value*[a]	95% CI[b]
Age, mean (SD) Missing= 4	57.4	(13.3)	55.4	(14.1)	57.5	(13.2)	***0.06***	-0.08-4.3
Smokers, n (%) Missing n= 33	498	(19.8)	26	(17.4)	472	(20.0)	*0.45*	
Females, n (%)	1491	(58.6)	85	(56.3)	1406	(58.7)	*0.56*	
Obesity[c], n (%) Missing= 114	589	(24.2)	40	(27.8)	549	(24.0)	*0.30*	
Received prophylactic antibiotic treatment, n (%) Missing n= 43	2492	(99.6)	144	(99.3)	2348	(99.6)	*0.64*	
Lower educational level[d], n (%) Missing n= 24	1746	(69.2)	102	(67.5)	1644	(69.3)	*0.64*	
Duration of operation, mean Minutes (SD) Missing= 28	175,7	(70.9)	185.9	(78.1)	175.1	(70.4)	***0.07***	-22.62-0.95
Previously operated in the back, n (%) Missing n= 19	1064	(41.1)	75	(49.7)	989	(41.6)	***0.05***	
Number of levels operated, mean (SD)	1,37	(0.70)	1.4	(0.8)	1.37	(0.7)	*0.30*	
Foreign language n, (%) Missing, n= 15	133	(5.3)	6	(4.0)	127	(5.3)	*0.47*	
Per-operative complications, n (%)	147	(5.8)	12	(7.9)	135	(5.6)	*0.24*	
Diabetes mellitus, n (%)	140	(5.5)	11	(7.3)	129	(5.4)	*0.32*	
Cancer disease, n (%)	59	(2.3)	3	(2.0)	56	(2.3)	*0.78*	
Osteoporosis, n (%)	81	(3.2)	3	(2.0)	78	(3.3)	*0.39*	
Fusion surgery, with instrumentation (%)	2218	(87.1)	135	(89.4)	2083	(87.0)	*0.39*	
Use of microscope or loupes, n (%)	1734	(68.1)	102	(67.5)	1632	(68.1)	*0.88*	
Use of wound drain, n (%) Missing, n= 72	1429	(57.8)	82	(56.9)	1347	(57.8)	*0.84*	
ASA Grade >2, n (%) [f] Missing n= 19	305	(12.1)	27	(18.0)	278	(11.7)	***0.02***	
Emergency surgery n(%) Missing n= 8	10	(0.4)	2	(1.3)	8	(0.3)	***0.06***	

Days of hospital stay, mean (SD) Missing= 491	6.1	(3.7)	7.7	(7.0)	6.0	(3.3)	***0.00***	-2.36-(-1.02)

[a] P-values of differences between SSI and no SSI (Student´s independent samples t-tests or Chi-square tests). [b] Confidence interval. [c] Obesity BMI>30 [d] No education from university/høgskole

3.2 Surgical site infection rate

Out of 151 SSI (5.9%): 116 (76.8%) were superficial and 48 (31.8%) were deep. Of the smokers 26 patients (5.2%) reported an SSI at 3 months' follow-up compared to 123 (6.1%) among the non-smokers (*p=0.45*). There was no difference in SSI rates between those who received prophylactic antibiotic treatment before surgery and those who did not (*p=0.64,* table 1). The rate of SSI were 142 (6.0%) in public and 9 (4.6%) in private hospitals (*p=0.42*).

Table 2. Characteristics of the study population at baseline, and among patients who were smokers and non-smokers

	All n= 2546		Smoker n= 498 Missing= 33		Non-smoker n= 2048		*P-value*[a]	95% CI[b]
Age, Mean (SD) Missing= 4	57.4	(13.3)	54.8	(11.5)	58.0	(13.6)	***0.00***	1.96-4.56
Surgical site infection (%)	151	(5.9)	26	(5.2)	123	(6.1)	*0.45*	
Females, n (%)	1491	(58.6)	289	(58.0)	1184	(58.8)	*0.77*	
Obesity[c], n (%) Missing= 114	589	(24.2)	98	(21.2)	484	(24.9)	***0.09***	
Received prophylactic antibiotic treatment, n (%) Missing n= 43	2492	(99.6)	486	(99.6)	1973	(99.5)	*0.89*	
Lower educational level[d], n (%) Missing n= 24	1746	(69.2)	391	(79.1)	1327	(66.5)	***0.00***	
Duration of operation, mean Minutes (SD) Missing= 28	175,7	(70.9)	174.2	(72.8)	176.0	(70.8)	*0.61*	-5.21-8.87
Previously operated in the back, n (%) Missing n= 19	1064	(41.1)	219	(44.3)	832	(41.5)	*0.26*	

Number of levels operated, mean (SD)	1,37	(0.70)	1.4	(0.7)	1.4	(0.7)	*0.59*	
Foreign language n, (%) Missing, n= 15	133	(5.3)	32	(6.5)	100	(5.0)	*0.18*	
Per-operative complications, n (%)	147	(5.8)	24	(4.8)	121	(6.0)	*0.31*	
Diabetes mellitus	140	(5.5)	26	(5.2)	111	(5.5)	*0.80*	
Cancer disease, n (%)	59	(2.3)	9	(1.8)	50	(2.5)	*0.37*	
Osteoporosis, n (%)	81	(3.2)	12	(2.4)	69	(3.4)	*0.25*	
Fusion surgery, with instrumentation (%)	2218	(87.1)	445	(89.4)	1744	(86.6)	*0.94*	
Use of microscope or loupes, n (%)	1734	(68.1)	338	(67.9)	1368	(67.9)	*0.99*	
Use of wound drain, n (%) Missing, n= 72	1429	(57.8)	262	(55.0)	1151	(58.6)	*0.16*	
ASA Grade >2, n (%) [d] Missing n= 19	305	(12.1)	55	(11.2)	248	(12.4)	*0.45*	
Emergency surgery n(%) Missing n= 8	10	(0.4)	3	(0.6)	6	(0.3)	*0.30*	
Days of hospital stay, mean (SD) Missing= 491	6.1	(3.7)	5.7	(3.3)	6.2	(3.8)	***0.01***	0.11-0.92

[a] P-values of differences between smokers and non-smokers (Student´s independent samples t-tests or Chi-square tests).
[b] Confidence interval. [c] Obesity BMI>30 [d] No education from university/høyskole.

3.3 Risk factors

No significant correlations (correlation coefficient ≥0.6) between the covariates were found (table 5, attached in the appendix). After performing univariate analysis, the risk factors: ASA grade >2, emergency surgery, days of hospital stay, previous back surgery, obesity, low educational level, duration of operation and age reached a level of significance (*p<0.1*) to be included in the multivariate analysis. Smoking which was the exposition variable was also included in the multivariate analysis even though it did not reach the preset statistical significance level (*p≤0.10*).

After the multivariate analysis; ASA grade >2 (OR 2.07, 95%CI= 1.19-3.60, *p=0.01*), days of hospital stay (OR 1,09, 95%CI=1.04-1.13, *p=0.00*) and lower age (OR 0.98, 95%CI=0.96-0.99 *p=<0.01*) were identified as independent risk factors for SSI. Since longer duration of hospital stay could be an indicator for early postoperative SSI and since we found a statistically

significant interaction between age and duration of hospital stay, we stratified the multivariate analyses by the latter variable (table 4). Patients with hospital admissions lasting longer than 9 days were obviously outliers according to the distribution of the data (figure 2, in attachments). There were 1800 (87.6%) patients who were hospitalized less than 10 days and the frequency of SSI was 98 (5.4%). There were 255 (12.4%) that were admitted for 10 days or more and of these 24 developed a SSI (9.4%). For the ones hospitalized more than 10 days, the risk for SSI almost doubled (OR 1.72, 95%CI= 1.04-2.82 *p=0.03*). A total of n=491 (19.3%) had missing data on duration of hospital stay.

Table 3 Risk factors for surgical site infection (SSI) at 3 month follow-up

Factors	OR[a]	95% CI[c]	*P-value*	OR[b]	95% CI[c]	*P-value*
ASA>2	1.66	1.07-2.56	*0.02*	2.07	1.19-3.60	*0.01*
Days of hospital stay	1.09	1.05-1.13	*0.00*	1.09	1.04-1.13	*0.00*
Age	0.99	0.98-1.00	*0.06*	0.98	0.96-0.99	*<0.01*
Emergency surgery	4.02	0.85-19.10	*0.08*			
Previously operated in the back	1.38	1.00-1.92	*0.05*			
Duration of operation	1.00	1.00-1.00	*0.07*			
Smoking	0.85	0.55-1.31	*0.45*			
Obesity	0.81	0.63-1.03	*0.09*			
Low educational level	0.52	0.41-0.66	*0.00*			

[a] Odds ratios for univariate analyses [b] Odds ratios for multivariate analyses [c] Confidence Interval

We checked for interaction between the variables and found an interaction between age and days of hospital stay, we therefore stratified the data on days of hospital stay; *less than 10 days* or *10 days or more*. The only independent risk factor for SSI in both groups, irrespective duration of hospital stay was ASA grade >2 (table 4). For patients admitted less than 10 days both one year lower age (OR= 0.98, 95%CI=0.96-0.94, *p<0.01*) and previously operated in the back (1.74, 95%CI= 1.13-2.69, *p=0.01*) were independent risk factors for SSI.

Table 4 Risk factors for surgical site infection (SSI) at 3 month follow-up, stratified on days of hospital stay [a]

	Hospital stay less than 10 days n= 1800			Hospital stay of 10 days or more n= 255		
	OR[b]	95% CI[c]	*P-value*	OR[b]	95% CI[c]	*P-value*
ASA>2	1.97	1.04-3.73	*0.04*	2.60	1.02-6.64	*0.04*
Age	0.98	0.96-0.99	*<0.01*			
Previously operated in the back	1.74	1.13-2.69	*0.01*			

[a] The same covariates were used as in table 3. [b] Odds ratios for multivariate analyses [c] Confidence interval

4 Discussion

4.1 Smokers vs non-smokers

The objectives of this study were to compare postoperative rate of infection among smokers and non-smokers within 3 months after fusion surgery for degenerative disorders of the lumbosacral spine, and to evaluate risk factors for SSI.

In our study the total rate of SSI three months after surgery was 5.9%, which is in line with findings in recent literature (8, 12-15). There was no statistically significant difference (*p=0.45*) in the rate of SSI between smokers (5.2%) and non-smokers (6.1%). This confirms our null-hypothesis that there is no difference in the SSI rate between smokers and non-smokers, which corresponds to a meta-analysis by Fei et al (33). A total of 33 persons were lacking information regarding smoking status (1.3%). In the SSI group there were 2 (1.3%) that did not respond to the question regarding smoking status, and 31 (1.3%) in the non-smoking group. It is therefore unlikely that the non-respondents represent a selection bias, regarding smoking habits. Something worth mentioning is that the non-smoking group at baseline were older, more obese and had a higher ASA-grade. This finding might indicate that surgeons could accept more comorbidity among the non-smokers.

4.3 ASA grade

The risk of developing SSI doubled with an increased comorbidity (ASA grade >2). Probably because systemic diseases make people more vulnerable for developing SSI. Previous case-control studies have also found higher ASA grade to be an independent risk factor for SSI (46-49), however a meta-analysis comprising of both cohorts and case-controls did not find this association (33). When smoking, a patient is automatically put in ASA group 2, despites having no systemic disease. This is due to an increased vulnerability for smokers, and higher risk of perioperative complications (50). Smoking can also cause systemic diseases such as chronic obstructive pulmonary disease (COPD) or heart disease which furthermore increases the ASA grade for these patients. However, in our study we did not find higher ASA grade >2 to be more frequent among smokers, but another study has (50).

4.4 Length of hospital stay

We found that longer duration of hospital stay was associated to postoperative SSI. Hospital stay longer than 10 days almost doubled the risk for SSI (OR= 1.7). It might seem like a paradox that by staying longer at the hospital, the chances of developing a SSI increases. However, there are reasons for being retained more than 10 days at the hospital. It might be reasons like complications, more intense postoperative pain, lack of mobilization, etc. All these factors might increase the risk of SSI, and those who develop early SSI are likely to stay longer at the hospital. The hospital population might be more vulnerable due to underlying health problems and exposure to nosocomial infections. Obviously, staying long term at the hospital in a room with other patients, can be unfortunate due to colonization of resistant hospital bacteria's, which makes an SSI more difficult to treat. The association between SSI and prolonged hospital stay has been documented in a previous study (31). Hence, avoiding prolonged hospital admissions could reduce SSI occurrence by complication avoidance, satisfactory postoperative analgesia and early mobilization, as well as a good dialogue between patient and surgeon for reassurance for an early return to home.

4.5 Age

Age was found to be an independent risk factor for SSI. Surprisingly, increasing age was not associated to increased risk of SSI. Among those with duration of hospital stay less than 10 days, there was a weak association between lower age and SSI (OR=0.98, 95%CI: 0.96-0.99, *p<0.01*). However, we regard this finding as incidental, and difficult to understand from a clinical perspective. Contrary to our findings, other studies have linked increasing age to be an independent risk factor for SSI (20, 23, 51).

4.6 Previously operated in the back

When stratifying the data on days of hospital stay, we found *previously operated in the back* to be an independent risk factor for the ones that stayed less than 10 days at the hospital. Reasons for this finding might be that previous surgery forms poorly vascularized scar tissue, complicating the surgery, thereby making the patient more susceptible for SSI. Difficulties with access might lead to the choice of another surgical procedure than what is standard, some approaches have in a previous study been found to increase the risk of SSI (47). The operation might last longer, exposing the open wound for a longer period of time, which might increase the risk of SSI.

4.7 Insignificant variables

In this study the vast majority (87.1%) of the operative procedures was supplemented by instrumentation. Despites the fact that use of instrumentation was more frequent in the SSI group, the difference between the two groups did not reach a level of significance (*p=0.39*): Thus, adding instrumentation to the fusion did not seem to increase the risk of SSI. Theoretically, instrumentation, representing a foreign body without blood supply, could be an important risk factor for SSI, and the use of implants has been known to increase the infection rates in previous studies (52, 53).

Surprisingly, diabetes was not found to be an independent risk factor of SSI. Despites we did not find diabetes to be a significant risk factor for SSI, several other studies have (20, 21, 23, 31, 33). Obesity has previously been addressed as a risk factor for developing SSI in spinal surgery (19,

47, 54-56), however we did not find any association. Objections to this finding is that information regarding BMI was missing in 114 patients, which might contribute to an underestimation of obesity as a risk factor if several of the ones missing actually were obese and had a SSI.

Duration of surgery reached the level of significance (*p=0.07*) to be included in the multivariate analysis, but when adjusted for other variables it did not qualify as an independent risk factor.

Number of operated levels was not associated with increased risk of SSI (*p=0.3*).

A reason why these known risk factors did not reach significant level, might be that the caregivers compensate for them, for instance by giving prolonged postoperative antibiotic prophylaxis. Unfortunately, we have no data that can support this assumption.

4.8 Limitations

This study has several limitations. As with other register-based studies, loss to follow up is higher than in limited and closely monitored clinical trials. In this study there were 1133 (30,8%) participants that did not respond at 3 months follow-up.

A previous study based on the NORspine registry showed that the ones that did not respond to the questionnaire in fact experienced less complications (57). SSI might therefore be overestimated when reported by the patient. However, patient reported complications might be more reliable as compared to complications reported by healthcare providers. A study by Öhrn et al. showed that SSI in the SWEspine were underreported by health workers (58, 59). SSI rates based upon postal mail responses from patients could in fact be less biased than those obtained from the hospital setting. Moreover, most SSI occurs after discharge of the hospital, which makes reporting by patients more reliable. Patients who forgot that they received antibiotic treatment for SSI, could represent recall bias. Unfortunately, there is no gold standard for how to collect data on postoperative SSI (58, 59).

Another limitation is that we do not have a microbiological diagnosis of SSI. A patient might be treated with antibiotics in the primary care, and in many cases antibiotic treatment is commenced before or without the microbiological sampling. Since diagnostic tests might be false positive/and negative, and since some receive antibiotics without microbiological

sampling, the true rate of SSI is difficult to assess. There might also be rare cases with a low virulent SSI that may develop after 3 months follow up. We do not have data on doses, duration or type of prophylactic antibiotic treatment used. However, a unpublished cross-sectional NORspine survey from 2010, showed that 85% of hospitals used intravenous Cephalothin (34).

No information regarding the daily amount of tobacco consumption among smokers were available and we had no data on the use of other tobacco products (e.g snuff). It was not possible to assess a dose-response relationship between smoking and risk of SSI.
Finally, there might obviously be other unobserved confounding factors, not accounted for in our study, that might influence the rate of surgical site infections.

An advantage of this study is its high external validity, since the data has been collected in daily clinical practice of multiple surgical units. Another strength is its design as a cohort study, which is the ideal study to evaluate risk factors. This study comprises a total of 2546 participants, which is by far larger than previous studies, apart from systematic reviews. No funding was received for the conduct of this study.

5 Conclusion

We found no increased risk for SSI among smokers. Patients with more comorbidity (ASA grade >2), those at risk for longer hospital stay and those previously operated with low back surgery should be informed that they are at higher risk of SSI. Attempts to avoid unnecessary prolonged hospital admissions could reduce SSI. Smoking cessation may however reduce cardiovascular comorbidity and thereby reduce the risk of SSI and other complications. This study highlights the importance of perioperative risk assessment.

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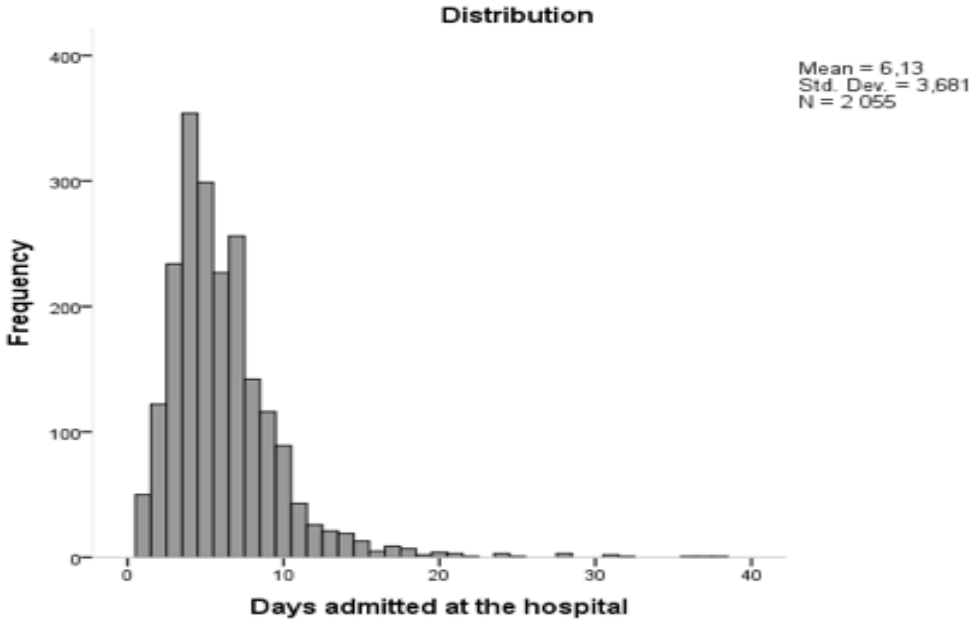
Tables

Table 5: Correlation between different variables										
	SSI	**ASA>2**	**DO**	**PS**	**E**	**DHS**	**Age**	**Obesity**	**Education**	**Smoking**
SSI	1	0.046 (p=0.02)	0.036 (p=0.07)	0.039 (p= 0.05)	0.038 (p=0.06)	0.109 (p=0.00)	-0.04 (p=0.06)	0.021 (p=0.30)	0.009 (p=0.64)	-0.01 (p=0.45)
ASA>2	0.046 (p=0.02)	1	0.06 (p=0.03)	0.09 (p=0.00)	0.01 (p=0.44)	0.124 (p=0.00)	0.288 (p=0.00)	0.064 (p=0.00)	-0.049 (p=0.01)	-0.01 (p=0.45)
Duration operation(DO)	0.036 (p=0.07)	0.060 (p=0.00)	1	0.093 (p=0.00)	-0.024 (p=0.23)	0.300 (p=0.00)	0.017 (p=0.40)	0.084 (p=0.00)	-0.028 p=(0.16)	-0.010 (p=0.61)
Previous backsurgery (PS)	0.039 (p= 0.05)	0.09 (p=0.00)	0.093 (p=0.00)	1	-0.003 (p=0.89)	0.084 (0.00)	0.049 (p=0.01)	0.062 (p=0.00)	-0-047 (p=0.02)	0.023 (p=0.26)
Emergency surgery (E)	0.038 (p=0.06)	0.01 (p=0.44)	-0.024 (p=0.23)	-0.003 (p=0.89)	1	-0.018 (p=0.42)	-0.015 (p=0.44)	-0.006 (p=0.76)	0.026 (p=0.19)	0.021 (p=0.30)
Days of hospitalstay(DHS)	0.109 (p=0.00)	0.124 (p=0.00)	0.300 (p=0.00)	0.084 (0.00)	-0.018 (p=0.42)	1	0.090 (p=0.00)	0.030 (p=0.18)	0.060 (p=0.00)	-0.055 (p=0.01)
Age	-0.04 (p=0.06)	0.288 (p=0.00)	0.017 (p=0.40)	0.049 (p=0.01)	-0.015 (p=0.44)	0.090 (p=0.00)	1	-0.22 (p=0.27)	-0.036 (p=0.07)	-0.097 (p=0.00)
Obestity	0.021 (p=0.30)	0.064 (p=0.00)	0.084 (p=0.00)	0.062 (p=0.00)	-0.006 (p=0.76)	0.030 (p=0.18)	-0.22 (p=0.27)	1	-0.034 (p=0.10)	-0.035 (p=0.09)
Education	0.009 (p=0.64)	-0.049 (p=0.01)	-0.028 p=(0.16)	-0-047 (p=0.02)	0.026 (p=0.19)	0.060 (p=0.00)	-0.036 (p=0.07)	-0.034 (p=0.10)	1	-0.109 (p=0.00)
Smoking	-0.01 (p=0.45)	-0.01 (p=0.45)	-0.010 (p=0.61)	0.023 (p=0.26)	0.021 (p=0.30)	-0.055 (p=0.01)	-0.097 (p=0.00)	-0.035 (p=0.09)	-0.109 (p=0.00)	1

Figures

Figure 2: distribution of days of hospital stay



Appendix

1. Patients questionnaire baseline

2. Patients questionnaire follow-up

3. Surgeons questionnaire

4. Approval from Research ethics committee (REC)

5. Summary of GRADE evaluation
   - "Risk factors for postoperative spinal wound infections after spinal decompression and fusion surgeries"
   - "Risk factors for surgical site infections among 1,772 patients operated on for lumbar disc herniation"
   - "Does daily tobacco smoking affect outcomes after microdecompression for degenerative central lumbar spinal stenosis?"
   - "Risk factors for surgical site infection following orthopaedic spinal operations"
   - "Effects of diabetes and smoking on lumbar spinal surgery outcomes"

1. Patients questionnaire baseline

SKJEMA 1A: PASIENTOPPLYSNINGER PREOPERATIVT
(Fylles ut av pasienten før operasjonen)

Spørreskjema for pasienter som skal opereres i ryggen

Nasjonalt Kvalitetsregister for Ryggkirurgi
Degenerativ rygg

Nasjonalt Kvalitetsregister for Ryggkirurgi
E-post: ryggregisteret@unn.no
Hjemmeside: www.ryggregisteret.no

1108 - Versjon 2

Pasientdata (Barkode)

Navn

Fødselsnr. (11 siffer)

Adresse

E-post
(For bruk ved etterkontroll)

Mobil
(For bruk ved etterkontroll)

Formålet med dette spørreskjemaet er å gi leger, sykepleiere og fysioterapeuter bedre forståelse av ryggpasienters plager og gi dem muligheter til å vurdere effekter av behandling. Din utfylling av skjemaet vil og være til stor nytte for å kunne gi et best mulig behandlingstilbud til ryggpasienter i fremtiden.

Spørreskjemaet har fire deler. Første del omhandler ulike sider ved din utdanning og familie samt dine smerter og plager. De neste delene består av tre ulike sett spørsmål for måling av din nåværende helse. Det første av disse (kalt Oswestry-skåre) måler hvordan ryggplagene påvirker dine dagligdagse gjøremål. Det andre (kalt EQ-5D) måler din helserelaterte livskvalitet. Den siste delen er en skala der du skal merke av hvor god eller dårlig din helsetilstand er.

Dato for utfylling
Dag Måned År

Røyker du? ☐ Ja ☐ Nei

Høyde og vekt

Høyde , (m) Vekt (kg)

Familie og barn

1. Sivilstatus (sett kun ett kryss) ☐ Gift
☐ Samboende
☐ Enslig

2. Hvor mange barn har du?

Utdanning og yrke

1. Hva er din høyeste fullførte utdanning? (Sett kun ett kryss)

☐ Grunnskole 7-10 år, framhaldsskole eller folkehøyskole
☐ Yrkesfaglig videregående skole, yrkesskole eller realskole
☐ Allmennfaglig videregående skole eller gymnas
☐ Høyskole eller universitet (mindre enn 4 år)
☐ Høyskole eller universitet (4 år eller mer)

Morsmål

☐ Norsk
☐ Samisk
☐ Annet, angi hvilket

.....

LUNDBLAD MEDIA AS, TROMSØ – O-102117

Hvor sterke smerter har du hatt siste uke?

Hvordan vil du gradere smertene du har hatt i rygg/hofte i løpet av den siste uken? Sett ring rundt ett tall.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Så vondt som det går an å ha

Hvordan vil du gradere de smertene du har hatt i benet (ett eller begge) i løpet av den siste uken? Sett ring rundt ett tall.

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Ingen smerter — Så vondt som det går an å ha

Funksjonsscore (Oswestry)

Disse spørsmålene er utarbeidet for å gi oss informasjon om hvordan dine smerter har påvirket dine muligheter til å klare dagliglivet ditt. Vær snill å besvare spørsmålene ved å sette kryss (kun ett kryss for hvert avsnitt) i de rutene som passer best for deg.

1. Smerte

- ☐ Jeg har ingen smerter for øyeblikket
- ☐ Smertene er veldig svake for øyeblikket
- ☐ Smertene er moderate for øyeblikket
- ☐ Smertene er temmelig sterke for øyeblikket
- ☐ Smertene er veldig sterke for øyeblikket
- ☐ Smertene er de verste jeg kan tenke meg for øyeblikket

2. Personlig stell

- ☐ Jeg kan stelle meg selv på vanlig måte uten at det forårsaker ekstra smerter
- ☐ Jeg kan stelle meg selv på vanlig måte, men det er veldig smertefullt
- ☐ Det er smertefullt å stelle seg selv, og jeg gjør det langsomt og forsiktig
- ☐ Jeg trenger noe hjelp, men klarer det meste av mitt personlige stell
- ☐ Jeg trenger hjelp hver dag til det meste av eget stell
- ☐ Jeg kler ikke på meg, har vanskeligheter med å vaske meg og holder sengen

3. Å løfte

- ☐ Jeg kan løfte tunge ting uten å få mer smerter
- ☐ Jeg kan løfte tunge ting, men får mer smerter
- ☐ Smertene hindrer meg i å løfte tunge ting opp fra gulvet, men jeg greier det hvis det som skal løftes er gunstig plassert, for eksempel på et bord
- ☐ Smertene hindrer meg i å løfte tunge ting, men jeg klarer lette og middels tunge ting, hvis det er gunstig plassert
- ☐ Jeg kan bare løfte noe som er veldig lett
- ☐ Jeg kan ikke løfte eller bære noe i det hele tatt

4. Å gå

- ☐ Smerter hindrer meg ikke i å gå i det hele tatt
- ☐ Smerter hindrer meg i å gå mer enn 1 ½ km
- ☐ Smerter hindrer meg i å gå mer enn ¾ km
- ☐ Smerter hindrer meg i å gå mer enn 100 m
- ☐ Jeg kan bare gå med stokk eller krykker
- ☐ Jeg ligger for det meste i sengen, og jeg må krabbe til toalettet

5. Å sitte

- ☐ Jeg kan sitte så lenge jeg vil i en hvilken som helst stol
- ☐ Jeg kan sitte så lenge jeg vil i min favorittstol
- ☐ Smerter hindrer meg i å sitte i mer enn en time
- ☐ Smerter hindrer meg i å sitte i mer enn en halv time
- ☐ Smerter hindrer meg i å sitte i mer enn ti minutter
- ☐ Smerter hindrer meg i å sitte i det hele tatt

6. Å stå

- ☐ Jeg kan stå så lenge jeg vil uten å få mer smerter
- ☐ Jeg kan stå så lenge jeg vil, men får mer smerter
- ☐ Smerter hindrer meg i å stå i mer enn en time
- ☐ Smerter hindrer meg i å stå i mer enn en halv time
- ☐ Smerter hindrer meg i å stå i mer enn ti minutter
- ☐ Smerter hindrer meg i å stå i det hele tatt

7. Å sove

- ☐ Søvnen min forstyrres aldri av smerter
- ☐ Søvnen min forstyrres av og til av smerter
- ☐ På grunn av smerter får jeg mindre enn seks timers søvn
- ☐ På grunn av smerter får jeg mindre enn fire timers søvn
- ☐ På grunn av smerter får jeg mindre enn to timers søvn
- ☐ Smerter hindrer all søvn

8. Seksualliv

- ☐ Seksuallivet mitt er normalt og forårsaker ikke mer smerter
- ☐ Seksuallivet mitt er normalt, men forårsaker noe mer smerter
- ☐ Seksuallivet mitt er normalt, men svært smertefullt
- ☐ Seksuallivet mitt er svært begrenset av smerter
- ☐ Seksuallivet mitt er nesten borte på grunn av smerter
- ☐ Smerter forhindrer alt seksualliv

9. Sosialt liv (omgang med venner og kjente)

- ☐ Det sosiale livet mitt er normalt og forårsaker ikke mer smerter
- ☐ Det sosiale livet mitt er normalt, men øker graden av smerter
- ☐ Smerter har ingen betydelig innvirkning på mitt sosiale liv, bortsett fra at de begrenser mine mer fysisk aktive sider, som sport osv.
- ☐ Smerter har begrenset mitt sosiale liv, og jeg går ikke så ofte ut
- ☐ Smerter har begrenset mitt sosiale liv til hjemmet
- ☐ På grunn av smerter har jeg ikke noe sosialt liv

10. Å reise

- ☐ Jeg kan reise hvor som helst uten smerter
- ☐ Jeg kan reise hvor som helst, men det gir mer smerter
- ☐ Smertene er ille, men jeg klarer reiser på to timer
- ☐ Smerter begrenser meg til korte reiser på under en time
- ☐ Smerter begrenser meg til korte, nødvendige reiser på under 30 minutter
- ☐ Smerter forhindrer meg fra å reise, unntatt for å få behandling

Beskrivelse av helsetilstand (EQ-5D)

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette kun ett kryss i en av rutene for hvert punkt nedenfor.

1. Gange

- ☐ Jeg har ingen problemer med å gå omkring
- ☐ Jeg har litt problemer med å gå omkring
- ☐ Jeg er sengeliggende

2. Personlig stell

- ☐ Jeg har ingen problemer med personlig stell
- ☐ Jeg har litt problemer med å vaske meg eller kle meg
- ☐ Jeg er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)

- ☐ Jeg har ingen problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har litt problemer med å utføre mine vanlige gjøremål
- ☐ Jeg er ute av stand til å utføre mine vanlige gjøremål

4. Smerte og ubehag

- ☐ Jeg har hverken smerte eller ubehag
- ☐ Jeg har moderat smerte eller ubehag
- ☐ Jeg har sterk smerte eller ubehag

5. Angst og depresjon

- ☐ Jeg er hverken engstelig eller deprimert
- ☐ Jeg er noe engstelig eller deprimert
- ☐ Jeg er svært engstelig eller deprimert

Smertestillende medisiner

Bruker du smertestillende medisiner på grunn av dine rygg- og/eller beinsmerter?

☐ Ja ☐ Nei

Hvis du har svart ja: Hvor ofte bruker du smertestillende medisiner? (Sett kun ett kryss)

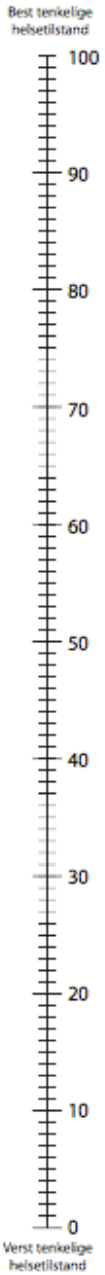
- ☐ Sjeldnere enn hver måned
- ☐ Hver måned
- ☐ Hver uke
- ☐ Daglig
- ☐ Flere ganger daglig

Helsetilstand

For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termometer), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.

Nåværende helsetilstand



Symptomvarighet

Varighet av nåværende rygg-/hoftesmerter(sett kun ett kryss):

- ☐ Jeg har ingen rygg-/hoftesmerter
- ☐ Mindre enn 3 måneder
- ☐ 3 til 12 måneder
- ☐ 1 til 2 år
- ☐ Mer enn 2 år

Varighet av nåværende utstrålende smerter:

- ☐ Jeg har ingen utstrålende smerter
- ☐ Mindre enn 3 måneder
- ☐ 3 til 12 måneder
- ☐ 1 til 2 år
- ☐ Mer enn 2 år

Varighet sykemelding/attføring/ rehabilitering pga aktuelle plager ☐☐☐ (uker)

Arbeidsstatus

- ☐ I arbeid
- ☐ Hjemmeværende, ulønnet
- ☐ Student/skoleelev
- ☐ Alderspensjonist
- ☐ Arbeidsledig
- ☐ Sykemeldt
- ☐ Aktivt sykemeldt
- ☐ Delvis sykemeldt ..... % sykemeldt
- ☐ Attføring/rehabilitering
- ☐ Uføretrygdet evt ..... % uføretrygdet

Har du søkt om uføretrygd?

(Sett kun ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

Har du søkt om erstatning fra forsikringsselskap eller folketrygden (eventuelt yrkesskadeerstatning)?

(Sett kun ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

2. Patients questionnaire follow-up

Pas. id

SKJEMA B1

Nasjonalt Kvalitetsregister for Ryggkirurgi

Degenerativ rygg

Nasjonalt Kvalitetsregister for Ryggkirurgi

Senter for Klinisk Dokumentasjon
og Evaluering - Helse Nord RHF

E-post: ryggregisteret@unn.no
Hjemmeside: www.ryggregisteret.no

Spørreskjema for pasienter 3 måneder etter ryggoperasjon

Formålet med dette spørreskjemaet er å gi leger, sykepleiere og fysioterapeuter bedre forståelse av ryggpasienters plager og å vurdere effekter av behandling. Din utfylling av skjemaet vil være til stor nytte for å kunne gi et best mulig behandlingstilbud til ryggpasienter i fremtiden.

Spørreskjemaet har fem deler. Første del omhandler dine smerter og plager. De neste delene består av tre ulike sett spørsmål for måling av din nåværende helse. Det første av disse (kalt Oswestry-skåre) måler hvordan ryggplagene påvirker dine dagligdagse gjøremål. Det andre (kalt EQ-5D) måler din helserelaterte livskvalitet, mens den neste er en skala der du skal merke av hvor god eller dårlig din helsetilstand er.

Vi ønsker også informasjon om eventuelle komplikasjoner som kan knyttes til inngrepet, samt trygd- og arbeidsstatus.

Dato for utfylling ☐☐.☐☐.☐☐
Dag Måned År

Hvilken nytte mener du at du har hatt av operasjon?

(Sett *kun ett* kryss)

- ☐ Jeg er helt bra
- ☐ Jeg er mye bedre
- ☐ Jeg er litt bedre
- ☐ Ingen forandring
- ☐ Jeg er litt verre
- ☐ Jeg er mye verre
- ☐ Jeg er verre enn noen gang før

Hvor fornøyd er du med behandlingen du har fått på sykehuset?

(Sett *kun ett* kryss)

- ☐ Fornøyd
- ☐ Litt fornøyd
- ☐ Hverken fornøyd eller misfornøyd
- ☐ Litt misfornøyd
- ☐ Misfornøyd

Hvor sterke smerter har du hatt siste uke?

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- ☐ Seksuallivet mitt er svært begrenset av smerter
- ☐ Seksuallivet mitt er nesten borte på grunn av smerter
- ☐ Smerter forhindrer alt seksualliv

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Pas. id

9. Sosialt liv (omgang med venner og kjente)

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Beskrivelse av helsetilstand (EQ-5D)

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3. Vanlige gjøremål

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- ☐ Jeg er svært engstelig eller deprimert

Smertestillende medisiner

Bruker du smertestillende medisiner på grunn av dine rygg- og/eller beinsmerter?

☐ Ja ☐ Nei

Hvis du har svart ja: Hvor ofte bruker du smertestillende medisiner? (Sett *kun ett* kryss)

- ☐ Sjeldnere enn hver måned
- ☐ Hver måned
- ☐ Hver uke
- ☐ Daglig
- ☐ Flere ganger daglig

Arbeidsstatus

- ☐ I arbeid
- ☐ Aktiv sykemeldt
- ☐ Hjemmeværende (ulønnet)
- ☐ Delvis sykemeldt
- ☐ Student/skoleelev ☐☐ % sykemeldt
- ☐ Alderspensjonist
- ☐ Attføring/rehabilitering
- ☐ Arbedisledig
- ☐ Uføretrygdet
- ☐ Sykemeldt evt. ☐☐ % uføretrygdet

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Helsetilstand

For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termometer), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.

Best tenkelige helsetilstand

100
90
80
70
60
50
40
30
20
10
0

Nåværende helsetilstand

Verst tenkelige helsetilstand

Pas. id

Friskmeldt? (tilbake i arbeid, helt eller delvis)

Hvis ja, angi dato ☐☐.☐☐.☐☐
Dag Måned År

Varighet av sykemelding etter operasjon ☐☐☐ (uker)

Komplikasjoner til inngrepet? (Sett evt. flere kryss)

- ☐ Oppsto det uventet blødning som medførte blod-overføring eller ny operasjon?
- ☐ Ble du behandlet med antibiotika for en urinveisinfeksjon i løpet av de nærmeste 4 ukene etter operasjonen?
- ☐ Ble du behandlet med antibiotika for en lungebetennelse i løpet av de nærmeste 4 ukene etter operasjonen?
- ☐ Har du i løpet av 3 måneder etter operasjonen, fått diagnosen "dyp vene trombose" (blodpropp i benet) og vært behandlet for dette?
- ☐ Har du i løpet av 3 måneder etter operasjonen, fått diagnosen lungeemboli (blodpropp i lungen) og blitt behandlet for dette?
- ☐ Ble du behandlet med antibiotika for en overfladisk infeksjon i operasjonssåret i løpet av de første 4 ukene etter operasjonen?
- ☐ Har du blitt eller blir du behandlet i over 6 uker med antibiotika for dyp infeksjon i operasjonssåret?
- ☐ Har du opplevd nytilkommet svakhet/lammelse i fot eller ben som kan tilskrives operasjonen?
- ☐ Har du som følge av operasjonen utviklet problemer med ufrivillig vannlating eller avføring?

Har du søkt om uføretrygd?

(Sett *kun ett* kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

Har du søkt om erstatning fra forsikringsselskap eller folketrygden (eventuelt yrkesskadeerstatning)?

(Sett *kun ett* kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

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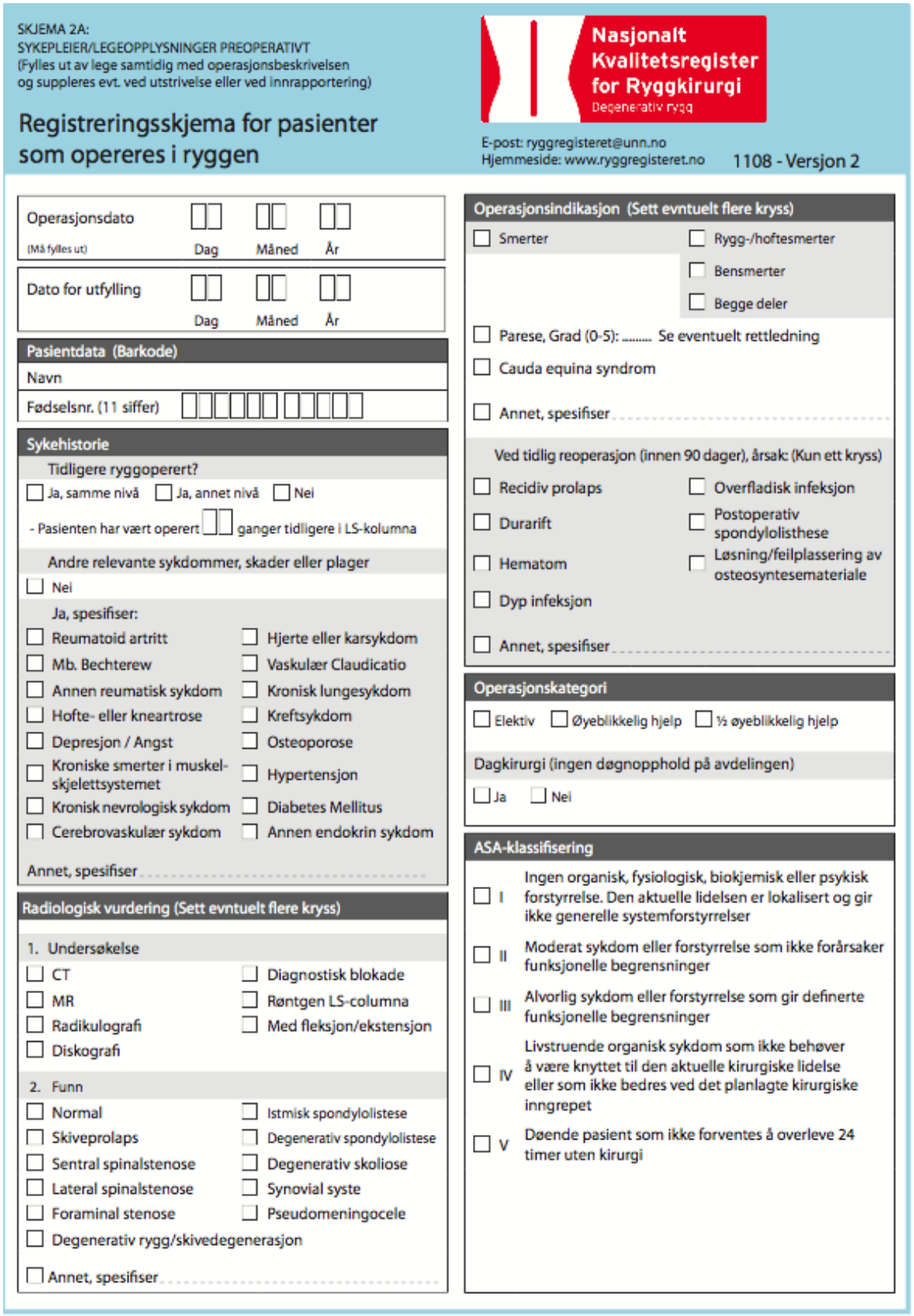
3. Surgeons questionnaire



SKJEMA 2A:
SYKEPLEIER/LEGEOPPLYSNINGER PREOPERATIVT
(Fylles ut av lege samtidig med operasjonsbeskrivelsen
og suppleres evt. ved utstrivelse eller ved innrapportering)

Registreringsskjema for pasienter som opereres i ryggen

Nasjonalt Kvalitetsregister for Ryggkirurgi
Degenerativ rygg

E-post: ryggregisteret@unn.no
Hjemmeside: www.ryggregisteret.no

1108 - Versjon 2

Operasjonsdato (Må fylles ut) Dag Måned År

Dato for utfylling Dag Måned År

Pasientdata (Barkode)

Navn

Fødselsnr. (11 siffer)

Sykehistorie

Tidligere ryggoperert?

☐ Ja, samme nivå ☐ Ja, annet nivå ☐ Nei

- Pasienten har vært operert ☐☐ ganger tidligere i LS-kolumna

Andre relevante sykdommer, skader eller plager

☐ Nei

Ja, spesifiser:

☐ Reumatoid artritt
☐ Mb. Bechterew
☐ Annen reumatisk sykdom
☐ Hofte- eller kneartrose
☐ Depresjon / Angst
☐ Kroniske smerter i muskel-skjelettsystemet
☐ Kronisk nevrologisk sykdom
☐ Cerebrovaskulær sykdom
☐ Hjerte eller karsykdom
☐ Vaskulær Claudicatio
☐ Kronisk lungesykdom
☐ Kreftsykdom
☐ Osteoporose
☐ Hypertensjon
☐ Diabetes Mellitus
☐ Annen endokrin sykdom

Annet, spesifiser .....

Radiologisk vurdering (Sett evntuelt flere kryss)

1. Undersøkelse

☐ CT
☐ MR
☐ Radikulografi
☐ Diskografi
☐ Diagnostisk blokade
☐ Røntgen LS-columna
☐ Med fleksjon/ekstensjon

2. Funn

☐ Normal
☐ Skiveprolaps
☐ Sentral spinalstenose
☐ Lateral spinalstenose
☐ Foraminal stenose
☐ Degenerativ rygg/skivedegenerasjon
☐ Istmisk spondylolistese
☐ Degenerativ spondylolistese
☐ Degenerativ skoliose
☐ Synovial syste
☐ Pseudomeningocele

☐ Annet, spesifiser .....

Operasjonsindikasjon (Sett evntuelt flere kryss)

☐ Smerter
☐ Rygg-/hoftesmerter
☐ Bensmerter
☐ Begge deler
☐ Parese, Grad (0-5): ..... Se eventuelt rettledning
☐ Cauda equina syndrom
☐ Annet, spesifiser .....

Ved tidlig reoperasjon (innen 90 dager), årsak: (Kun ett kryss)

☐ Recidiv prolaps
☐ Durarift
☐ Hematom
☐ Dyp infeksjon
☐ Overfladisk infeksjon
☐ Postoperativ spondylolisthese
☐ Løsning/feilplassering av osteosyntesemateriale
☐ Annet, spesifiser .....

Operasjonskategori

☐ Elektiv ☐ Øyeblikkelig hjelp ☐ ½ øyeblikkelig hjelp

Dagkirurgi (ingen døgnopphold på avdelingen)

☐ Ja ☐ Nei

ASA-klassifisering

☐ I Ingen organisk, fysiologisk, biokjemisk eller psykisk forstyrrelse. Den aktuelle lidelsen er lokalisert og gir ikke generelle systemforstyrrelser

☐ II Moderat sykdom eller forstyrrelse som ikke forårsaker funksjonelle begrensninger

☐ III Alvorlig sykdom eller forstyrrelse som gir definerte funksjonelle begrensninger

☐ IV Livstruende organisk sykdom som ikke behøver å være knyttet til den aktuelle kirurgiske lidelse eller som ikke bedres ved det planlagte kirurgiske inngrepet

☐ V Døende pasient som ikke forventes å overleve 24 timer uten kirurgi

Operasjonsmetode (Sett evt. flere kryss)

Har operatøren brukt mikroskop eller lupebriller?

☐ Ja ☐ Nei

Prolapsekstirpasjon?

☐ Nei

☐ Ja, med tømming av skive (diskektomi)

☐ Ja, uten tømming av skive

Kirurgisk dekompresjon

☐ Dekompresjon med bevaring av midtlinjestrukturer
- ☐ Unilateral
- ☐ Bilateral med unilateral tilgang
- ☐ Bilateral med bilateral tilgang

☐ Laminektomi

☐ Fasettektomi i ett eller flere nivåer
- ☐ Unilateral
- ☐ Bilateral

Andre operasjonsmetoder

☐ Endoskopi
☐ Minimal invasiv prosedyre (tube kirurgi)
☐ Ekspanderende interspinøst implantat
☐ Fjerning av ekspanderende interspinøst implantat
☐ Skiveprotese
☐ Nukleus implantat
☐ Nukleutomi
☐ Kjemonukleolyse
☐ Revisjon av osteosyntesematerialet
☐ Fjerning av osteosyntesemateriale

Annet, spesifiser .....

Tilgang:

☐ Midtlinje
☐ Lateral tilgang (Wiltze)
☐ Fremre

Ved fusjonskirurgi (Sett eventuelt flere kryss)

☐ Posterolateral fusjon
- ☐ Instrumentell
- ☐ Bengraft

☐ ALIF
- ☐ Bur (cage)
- ☐ Benblokk i skiverom

☐ PLIF
- ☐ Bur (cage)
- ☐ Kun benblokk

☐ TLIF
- ☐ Bur (cage)
- ☐ Kun benblokk

Annet, spesifiser .....

Type bengraft

☐ Autograft
☐ Bensubstitutt
☐ Bank-ben

Operert nivå og side (Sett eventuelt flere kryss)

☐ L2/3	☐ Hø.	☐ Ve.
☐ L3/4	☐ Hø.	☐ Ve.
☐ L4/5	☐ Hø.	☐ Ve.
☐ L5/S1	☐ Hø.	☐ Ve.

Annet, spesifiser .....

Antibiotikaprofylakse

☐ Ja ☐ Nei

Sårdren

☐ Ja ☐ Nei

Knivtid (hud til hud)

Opr. start ☐☐ ☐☐ (timer/min)

Opr. slutt ☐☐ ☐☐ (timer/min)

Evt. samlet knivtid (kalkuleres atuomatisk). ☐☐ ☐☐ (timer/min)

Peroperative komplikasjoner:

☐ Durarift/liquorlekasje
☐ Nerverotskade
☐ Operert på feil nivå/side
☐ Feil plassering av implantat
☐ Transfusjonskrevende peroperativ blødning
☐ Respiratoriske komplikasjoner
☐ Kardiovaskulære komplikasjone
☐ Anafylaktisk reaksjon
☐ Annet, spesifiser .....

Oppgi inntil to operasjonskoder som best beskriver inngrepet (NCSP):

☐☐☐ ☐☐

☐☐☐ ☐☐

Fylles ut ved endt opphold/utskrivelse

Antall liggedøgn i forbindelse med inngrepet

☐☐☐ (dager)

Ved dødsfall under oppholdet, oppgi årsak (Kun ett kryss)

☐ Cardiogen årsak
☐ Lumgeemboli
☐ Pneumoni
☐ Annen infeksjon
☐ Anafylaksi
☐ Cerebrovaskulær årsak
☐ Blødning
☐ Annet, spesifiser .....

4. Approval from Research ethics committee (REC)

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord	[redacted]		01.09.2017	[redacted]
			Deres dato:	Deres referanse:
			08.08.2017	

Vår referanse må oppgis ved alle henvendelser

[redacted]
Nevrokirurgisk avd

2017/1648 Er røyking assosiert til postoperativ sårinfeksjon etter avstivningsoperasjon for degenerative tilstander i korsryggen

Forskningsansvarlig: UiT - Norges arktiske universitet
Prosjektleder: [redacted]

Søknaden er behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK nord) ved sekretariatsleder, på fullmakt gitt av komiteen med hjemmel i forskningsetikkforskriften § 10 annet ledd.

Prosjektleders prosjektomtale
Det er uklart om røyking er assosiert til postoperativ sårinfeksjon etter ryggkirurgi. Studien tar sikte på å besvare dette spørsmålet. Kohortstudie, basert på data fra Nasjonalt kvalitetsregister for ryggkirurgi. Data fra flere tusen ryggopererte vil bli analysert ved bruk av multivariansanalyser. Eksposisjon (primær risikofaktor) er røyking, og sammenhengen mellom denne variabelen og pasientrapportert sårinfeksjon (ja/nei) tre måneder etter operasjon, vil bli justert for potensielt konfunderende faktorer (andre forhold som kan være av betydning for sårinfeksjon: bruk av antibiotika,demografi, livsstil, symptomvarighet og komorbiditet)

Om prosjektet
Det beskrives i søknaden at «Det er uklart om røyking er assosiert til postoperativ sårinfeksjon etter ryggkirurgi. Studien tar sikte på å besvare dette spørsmålet. Kohortstudie, basert på data fra Nasjonalt kvalitetsregister for ryggkirurgi. Data fra flere tusen ryggopererte vil bli analysert ved bruk av multivariansanalyser. Eksposisjon (primær risikofaktor) er røyking, og sammenhengen mellom denne variabelen og pasientrapportert sårinfeksjon (ja/nei) tre måneder etter operasjon, vil bli justert for potensielt konfunderende faktorer (andre forhold som kan være av betydning for sårinfeksjon: bruk av antibiotika,demografi, livsstil, symptomvarighet og komorbiditet)

Data som skal samles inn er data på demografi, livsstilsfaktorer, yrkesdeltakelse, trygdestatus, pasientrapporterte utfallsmål, legeopplysninger: diagnose, behandling, komorbiditet

Vurdering av om de avgitte samtykkene er dekkende for denne studien.
Det fremgår av det avgitte samtykket at «Forskere vil kunne bruke registeret til å evaluere blant annet hva som har betydning for gode eller dårlige operasjonsresultat, hvilken betydning behandlingen har i relasjon til trygde-, og sosialmedisinske forhold og i forhold til helseøkonomi.»

REK har vurdert at dette er dekkende for det som skal gjøres i den omsøkte studien.

Vedtak
Med hjemmel i helseforskningsloven § 2 og 10 godkjennes prosjektet.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK nord på eget skjema senest 16.12.2018, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK nord dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK nord. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK nord, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

[redacted]
Sekretariatsleder

[redacted]
seniorrådgiver

Kopi til: [redacted]

5. Summary of grade evaluation

Referanse: Habiba S, Nygaard OP, Brox JI, Hellum C, Austevoll IM, Solberg TK. Risk factors for surgical site infections among 1,772 patients operated on for lumbar disc herniation: a multicentre observational registry-based study. Acta Neurochir (Wien). 2017;159(6):1113-8.

Grade: Moderate ⊕⊕⊕	
Documentation:	III
Recommendation:	C

Aim of study	Methods and materials	Results	Discussion/comments
To evaluate risk factors for SSI after less invasive lumbar disc surgery and the effectiveness of PAT. **Conclusion** Support to the use of PAT in surgery for lumbar disc herniation. NNT have PAT to avoid one SSI was 43. **Country:** **Norway** **Year:** Oct 2006-sept 2009	**Study design**: prospective cohorte. Register based observational study **Inclusion:** *Lumbar disc herniation 1 level * Included in NORspine **Exclusion:** * Laminectomy/fusion * More than 1 lever operated *Missing 3month follow-up **Outcome:** * Surgical site infection at 3 months based on a clinical review of the patient history, medical records and a physical examination. **Adjusted variables:** Use of PAT, long duration of surgery, emergency surgery, and higher BMI **Statistical methods:** t-test (numerical), chi-square (categorical). Univariate/multivariate regression analysis.	A cohort of 1,772 consecutive patients. Three months after surgery, 2.3% had developed a SSI. Independent risk factors for SSI were found to be: No prophylactic antibiotics (PAT) and long duration of surgery. Among 1,294 (73.0%) who received PAT, 22 (1.7%) had SSI compared with 18 (4.0%) of the patients who did not receive PAT (p = 0.005). No PAT increased the risk of SSI with 5.3 times (OR = 5.3, 95% CI = 2.2–12.7, p< 0.001). Number needed to have PAT to avoid one SSI were 43. **Table 3** Risk factors for surgical site infection (SSI) at 3 months of follow-up The risk was threefold for patients operated on for more than 1 h and fivefold for those not receiving PAT, for developing SSI. The SSI rate was similar for private and public hospitals. Loss to follow-up was 22.9% (n=525).	**Comparable groups at baseline?** Yes, but higher rate of obese among the SSI group. **Recruited from the same population/sample group?** Yes, NORspine **Were the exposed individuals representative for a defined sample population?** Yes **Prospective?** Yes **Were exposition and outcome measured equal for the groups?** Yes **Follow-up high enough?** A total of 73%, which is quite good for a cohort study. **Accounted for loss to follow up?** 22.9% were lost to follow up, did not answer the questionnaire at 3 months. **Long enough follow-up for positive/negative outcomes?** Yes, SSI at 3 months were outcome measure. However one can also develop deep-SSI after 3 months of surgery, but this is rare. **Accounted for confounding factors?** Yes **The ones that considered outcome, were they blinded?** No **Strengths:** large sample size, prospective study, many different variables included, **Weaknesses:** Loss to follow up (23%), SSI based on clinical judgment no microbial diagnosis

Factors	OR [a]	95% CI	*p* value	OR [b]	95% CI	*p* value
No prophylactic antibiotic treatment	2.4	(1.3–4.5)	0.007	5.3	(2.2–12.7)	<0.001
Duration of surgery [c] above mean (>68 min)	1.6	(0.9–3.2	0.1	2.8	(1.2–6.6)	0.02
BMI obesity [d]	1.8	(0.8–4.8)	0.1	1.7	(0.7–4.3)	0.2
Use of microscope or loupes	0.5	(0.2–1.1)	0.08	0.7	(0.3–1.7)	0.4
Emergency surgery	1.7	(0.7–4.5)	0.3			
Age	1.0	(1.0–1.0)	0.06			
Smoker	0.8	(0.4–1.6)	1.0			
Previously operated on the same level	0.8	(0.3–3.1)	0.7			
ASA grade >II	0.5	(0.7–3.9)	0.5			
Discectomy	1.5	(0.8–2.8)	0.3			
High school educational level [e]	0.8	(0.4–1.5)	0.5			

Referanse: Gulati S, Nordseth T, Nerland US, Gulati M, Weber C, Giannadakis C, et al. Does daily tobacco smoking affect outcomes after microdecompression for degenerative central lumbar spinal stenosis? - A multicenter observational registry-based study. Acta Neurochir	Grade: Low/Moderate ⊕⊕(⊕)
	Documentation: III
	Recommendation: C

Aim of study	Methods and materials	Results	Discussion/comments
To examine the relationship between daily smoking and patient-reported outcome at 1 year using the Oswestry Disability Index (ODI) after microdecompression **Conclusion** Nonsmokers experienced a significantly larger improvement at 1 year following microdecompression for LSS compared to smokers. Smokers were less likely to achieve a minimal clinically important difference. **Country:** **Norway** **Year:** Oct 2006- Dec 2011	**Study design:** Prospective cohort. Multicenter observational register based study. **Data collection:** From the NORspine registry. **Inclusion:** Diagnosis of central LSS, Scheduled operation in ≤2 lumbar levels with bilateral microdecompression or unilateral microdecompression for bilateral decompression in the time period between October 2006 and December 2011. 3. Included in the NORspine registry. **Exclusion:** 1. Discectomy as part of the decompression. 2. Fusion surgery. **Outcome:** patient-reported outcome at 1 year using the Oswestry Disability Index (ODI), Length of hospital stay, Peri/postoperative complication rates **Adjusted variables:** age, sex, BMI, preoperative ODI, prior surgery, educational level **Statistical methods:** t-test, chi-square test. Univariate analysis. Multivariate logistic regression. **Missing data:** cases excluded pairwise. Last observation carried forward.	825 patients were enrolled out of 2745 screened. There were 619 nonsmokers and 206 smokers. There was a significant difference in ODI change at 1 year between non- smokers and smokers (4.2 points, 95 % CI 0.98–7.34, p= 0.010). At 1 year 69.6 % of nonsmokers had achieved a minimal clinically important difference, defined as ≥10 point improvement in ODI, compared to 60.8 % of smokers (p= 0.039). There was no difference between nonsmokers and smokers in the overall complication rate (11.6 % vs. 9.2 %, p = 0.34). There was no difference between nonsmokers and smokers in the length of hospital stays for either single-level (2.3 vs. 2.2 days, p = 0.99) or two-level (3.1 vs. 2.3 days, p = 0.175) microdecompression. Loss to follow up was as high as 21.5%, these were accounted for by referring to another study that looked at the ones that where lost to follow up in the NORspine registry. **Table 3** Multiple regression analysis with a difference in ODI 12 months after surgery as the dependent variable Variable / Complete case analysis: Parameter estimate; 95 % Confidence interval; *P*-value / Last observation carried forward: Parameter estimate; 95 % Confidence interval; *P*-value Intercept: 12.8; 1.25, 24.35; 0.03 / 9.4; −1.11, 19.92; 0.08 Smoker: −5.3; −8.40, −2.10; 0.001 / −4.3; −7.22, −1.35; 0.004 [a]Oswestry score 21–40, pre-surgery: 10.5; 5.92, 15.05; <0.001 / 9.9; 5.56, 14.21; <0.001 [a]Oswestry score 41–60, pre-surgery: 16.5; 11.67, 21.25; <0.001 / 15.8; 11.30, 20.37; <0.001 [a]Oswestry score>60, pre-surgery: 33.1; , 39.41; <0.001 / 31.5; 25.62, 37.34; <0.001 Age (per 10 year): −0.9; −2.39, 0.59; 0.237 / −0.5; −1.90, 0.81; 0.434 Female sex: 2.3; −0.37, 4.99; 0.091 / 1.7; −0.77, 4.26; 0.173 Attended college: 3.0; 0.02, 6.00; 0.048 / 2.7; −0.09, 5.49; 0.057 Previous lumbar spine surgery: −8.3; −11.72, −4.89; <0.001 / −7.3; −10.57, −4.08; <0.001 [b]Body mass index 25–29.9 kg/m^2: −0.6; −3.73, 2.49; 0.697 / −0.5; −2.41, 3.43; 0.733 [b]Body mass index 30–34.9 kg/m^2: −4.6; −8.67, −0.62; 0.024 / −2.9; −6.57, 0.84; 0.130 [b]Body mass index≥35 kg/m^2: −13.2; −19.98, −6.40; <0.001 / −10.6; −17.15, −4.10; 0.001	**Comparable groups at baseline?** Yes, but smokers had a higher ASA grade at baseline **Recruited from the same population/sample group?** Yes, NORspine registry **Were the exposed individuals representative for a defined sample population?** Yes **Prospective?** Yes **Were exposition and outcome measured equal for the groups?** Yes **Follow-up?** One year follow up. 78.5% responded. **Accounted for loss to follow up?** Well, referred to another study which does. **Long enough follow-up for positive/negative outcomes?** Yes **Accounted for confounding factors?** Probably many missing **The ones that considered outcome, were they blinded?** Yes **Strengths:** specific inclusion/exclusion criteria, large sample size, prospective data, **Weaknesses:** Loss to follow up is high, not checked for interactions, no dose-response relationship, probably other confounding factors

Referanse: Veeravagu A, Patil CG, Lad SP, Boakye M. Risk factors for postoperative spinal wound infections after spinal decompression and fusion surgeries. *Spine (Phila Pa 1976)*. 2009;34(17):1869-1872	Grade: Low/moderate ⊕ ⊕(⊕)
	Documentation: III
	Recommendation: C

Aim of study	Methods and materials	Results	Discussion/comments
To determine preoperative, intraoperative, and patient characteristics that contribute to an increased risk of postoperative wound infection in patients undergoing spinal surgery. **Conclusion** Postoperative infection is associated with greater length of hospital stay, increased mortality, and increased complication rates. **Country:** **USA** **Year:** 1997-2006	**Study design:** prospective cohorte data from a multicenter from the Veterans Affairs' National Surgical Quality Improvement Program database **Data collection:** prospectively collected database, Veterans (Affairs' NSQIP) 123 VA hospitals across the country of USA **Inclusion:** * All patients who underwent a spinal surgery (decompression, fusion, or instrumentation) * Opr. between 1997 and 2006 * ICD-9 codes of appropriate patients **Outcome:** postoperative infection within 30 days of discharge from the hospital. Secondary outcomes were com- plication rate, total length of hospital stay after spinal surgery, and mortality **Adjusted variables:** diabetes, smoking, ASA class, weight loss, functional status, transfusion, disseminated cancer, fusion, duration of surgery, hematocrit, steroid use, sepsis **Statistical methods:** Bivariate analysis, X^2 and Fischer exact test for categorical variables, multivariate logistic regression.	Data on 24,774 patients were analyzed. 752 patients (3.04%) had a postoperative wound infection. Postoperative wound infection patients had a longer hospital stay (7.12 *vs.* 4.20 days), higher mortality (1.06% *vs.* 0.5%) and higher return to the operating room rates (37% *vs.* 2.45%) compared to those without postoperative wound infection. **Table 5. Multivariate Analysis of Risk Factors for Infection After Spinal Decompression, Fusion, and Instrumentation** Variable / OR / 95% Confidence Intervals Diabetes No or diet controlled* — — Oral 0.89 0.68–1.16 Insulin 1.5 1.13–2.00† Current smoker No* — — Yes 1.19 1.02–1.37† ASA class 1–2* — — 3 1.45 1.24–1.70† 4–5 1.66 1.14–2.44† Weight loss No* — — Yes 2.14 1.35–3.39† Functional status Independent* — — Dependent 1.36 1.06–1.74† Intraoperative transfusion No* — — Yes 1.42 1.07–1.90† Disseminated cancer No* — — Yes 1.83 1.00–3.35† Fusion No* — — Yes 1.24 1.03–1.49† Operative duration (h) <3* — — 3–6 1.33 1.12–1.58† >6 1.40 1.02–1.93† *Reference group. †Statistically significant value. Multivariate logistic regression identified insulin dependent diabetes (odds ratios [OR] 1.50), current smoking (OR 1.19) ASA class of 3 (OR 1.45) or 4 to 5 (OR 1.66), weight loss (OR 2.14), dependent functional status (1.36) preoperative HCT 36 (1.37), disseminated cancer (1.83), fusion (OR 1.24) and an operative duration of 3 to 6 hours (OR 1.33) or 6 hours (OR 1.40) as statistically significant predictors of postoperative infection. Anemia found as an preoperative independent risk factor for SSI.	**Comparable groups at baseline?** Tables not shown **Recruited from the same population/sample group?** Yes **Was the exposed individual's representative for a defined sample population?** Yes, however it is important to state that in this study the study comprises a total of 94.8% men. Which makes the general applicability low. **Prospective?** Yes **Were exposition and outcome measured equal for the groups?** Yes **Follow-up high enough?** Not accounted for **Accounted for loss to follow up?** No **Long enough follow-up for positive/negative outcomes?** Yes, however some might develop a SSI after 1 month, especially the deep SSI. **Accounted for confounding factors?** Yes **The ones that considered outcome, were they blinded?** No. **Strengths:** large sample size, prospective data, **Weaknesses:** almost only men included in the study, not discussed limitations, not blinded, no comparison between groups at baseline

Referanse: S.Appaduray, P.Lo **Effects of diabetes and smoking on lumbar spinal surgery outcomes**. Journal of clinical neuroscience 2013; 20:1713-17	Grade: Low/moderate ⊕⊕(⊕)	
	Documentation:	III
	Recommendation:	C

Aim of the study	Methods and materials	Results	Discussion/comments
To assess the effects of smoking and diabetes on the surgical outcome in lumbar spinal surgery **Conclusion** Diabetes increase the rate of poor outcome following lumbar spinal surgery. Smoking was not associated with poor outcome. **Country** **Australia** **Year** 2001-2005	Study design: retrospective cohorte with extraction of patient information from clinical notes. Study with four cohorts formed: • Non diabetic but positive smoking history • Diabetic and positive smoking history • Diabetic but non smoker • Control: non DIA non smoker Inclusion: • Lumbar spine surgery (lumbar stenosis, prolapsed discs in the lumbar region, thoracolumbar scoliosis) • Minimum 1 year follow up Exclusion: • Incomplete follow up Outcome: • Infectious complications • Cardiovascular complications • Other complications (post hemorrhagic anemia, atelectasis, hyperkalemia, obstruction, urine retention, wound pain>6mnd postop) Adjusted variables: age, sex, diabetes/smoking status, comorbidities, type of surgery. Statistic methods: Fishers test, Kruskal-wallis test, Multivariate logistic regression	75 patients in the diabetic group. 40 patients with positive smoking history and diabetes. 343 patients with positive smoking history. And 444 patients in the control group. Patients in both the groups with patients with diabetes had a higher risk of complications compared to the two other groups. Diabetes was found to be an independent risk factor for infectious complications (OR=2,10), cardiovascular complications (OR= 2,25). Also the patients age was found to be a significant risk factor for infection (OR=1,02), cardiovascular complications (OR= 1,02) and other complications (1,01). Patients who underwent spinal fusion had higher complication rates than those who underwent decompression surgery. Positive smoking history was not in this study found to increase the risk of any complications on surgical outcome, not for: * Single complication OR= 1,01 p=9,42 * Multiple complications OR= 0,88 p=0,69 * Infectious complications OR= 0,69 p=0,174 * Other complications OR= 0,585	**Were the groups comparable compared to important background factors:** No, the patients in the two diabetic groups was significantly older than the other groups. The average in the diabetic group was 68+/- 9,5 and the average in the control group was 54+/- 19. **Is the groups recruited from the same population:** Yes, they were all selected from the electronic database using procedure codes/diagnostic codes. **Was exposed individuals representative of a defined population group / population:** Yes. **Prospective study:** No, retrospective. **Did exposure and outcome get measured equally in the different groups:** Yes **Where enough people in the cohort followed up:** Yes, the inclusion criteria was at least 1 year follow up. **Is it done accounts for loss to follow up:** The ones that had incomplete follow up was excluded from the study. **Was the follow-up long enough to show results:** Yes, the study went over 4 years, which is enough to say something about postoperative complications. **Confounding factors:** Adjusted for **Blinded:** Not relevant **Strengths:** Long follow-up, moderate study group, **Weaknesses:** retrospective, based on clinical notes, potential recording bias (more likely to get a diabetes or smoking diagnosis if complication), unknown duration and frequency of smoking, single center study

Referanse: Olsen MA, Nepple JJ, Riew KD, Lenke LG, Bridwell KH, Mayfield J, et al. Risk factors for surgical site infection following orthopaedic spinal operations. J Bone Joint Surg Am. 2008;90(1):62-9.			Grade: Low ⊕⊕ Documentation: III Recommendation: C
Aim of study	**Methods and materials**	**Results**	**Discussion/comments**
to determine independent risk factors for surgical site infection following orthopedic spinal operations. **Conclusion** Diabetes was associated with the highest independent risk of spinal surgical site infection. Also suboptimal timing of PAT, elevated serum glucose, obesity were independent risk factors. **Country:** **USA** **Year:** 1998-2002	**Study design:** retrospective case-control study Data collection: collected from the medical records by two investigators, using a standardized data collection form. **Inclusion:** * Laminectomy, discectomy, and/or spinal arthrodesis * from Jan -98 through Dec -02. * Operated by orthopedic surgeon **Exclusion:** * Spine surgery operated by neurosurgeon * <15 years * Admission code of either: intraspinal abscess, osteomyelitis, SSI **Outcome:** Surgical site infection (yes/no): any physician diagnosis of surgical site infection * ICD-9CM Code of infection * readmission diagnosis of infection * positive microbiological cultures of specimens from the wound Adjusted variables: **Statistical methods:** t-test and chi-square test. Univariate analysis and multiple logistic regression.	Surgical site infection rate following orthopedic spinal operations was 2.0% (46 of 2316). Univariate analysis: obesity (OR 4.5 p=0.001), diabetes (OR=8.4, p=<0.001), ASA 3 and 4 (OR=2.6, p=0.003), posterior approach (OR= 3.4, p=0.020), suboptimal timing of prophylactic AB (OR=3.1, p=0.002), duration of operation >75th percentile (OR=2.4, p=0.012), >2 resident surgeons (OR= 2.5, p=0.008) were factors that came out significant. However, after multivariate analysis only diabetes (OR= 3.5, p=0.020), suboptimal timing of PAT (OR=3.4, p=0.005), Elevated serum glucose level preoperatively or postoperatively (OR=3.3, p= 0.005), obesity (OR=2.2, p=0.034), cervical levels (OR= 0.3, p=0.002). The median time from the operation to the diagnosis of the infection was eleven days, with a minimum of two days and a maximum of 236 days for a patient with osteomyelitis.	**Were the case-control groups recruited from similar population groups?** Yes **Comparable groups based on baseline characteristics?** Only baseline characteristics for the whole patient material were displayed, not for each group. **Is the case-groups condition adequate described/diagnosis validated?** Yes, use of ICD codes of SSI. **Are the control-group free of the condition/diagnosis?** Yes **Accounted for important confounding factors?** Yes **Is the exposure equally measured for the groups?** Yes **Blinded?** No **Were the response-rate equal in both groups?** Yes **Strengths:** wide variety of potential risk factors, relatively large number of patients in total with spinal surgical site infection **Weaknesses:** single center study, retrospective case-control, few SSI cases, baseline characteristics for the two groups not compared, based on medical records