Cycle 1: Disability due to back pain despite conservative therapy

1. General Reference on Low Back Pain

2. General Reference on Low Back Pain

Abstract

Low back pain is a very common symptom. It occurs in high-income, middle-income, and low-income countries and all age groups from children to the elderly population. Globally, years lived with disability caused by low back pain increased by 54% between 1990 and 2015, mainly because of population increase and ageing, with the biggest increase seen in low-income and middle-income countries. Low back pain is now the leading cause of disability worldwide. For nearly all people with low back pain, it is not possible to identify a specific nociceptive cause. Only a small proportion of people have a well understood pathological cause—e.g., a vertebral fracture, malignancy, or infection. People with physically demanding jobs, physical and mental comorbidities, smokers, and obese individuals are at greatest risk of reporting low back pain. Disabling low back pain is over-represented among people with low socioeconomic status. Most people with new episodes of low back pain recover quickly; however, recurrence is common and in a small proportion of people, low back pain becomes persistent and disabling. Initial high pain intensity, psychological distress, and accompanying pain at multiple body sites increases the risk of persistent disabling low back pain. Increasing evidence shows that central pain-modulating mechanisms and pain cognitions have important roles in the development of persistent disabling low back pain. Cost, healthcare use, and disability from low back pain vary substantially between countries and are influenced by local culture and social systems, as well as by beliefs about cause and effect. Disability costs attributed to low back pain are projected to increase in coming decades, in particular in low-income and middle-income countries, where health and other systems are often fragile and not equipped to cope with the growing burden. Intensified research efforts and global initiatives are clearly needed to address the burdens of low back pain as a public health problem.

Narrative review with 121 citations focused on long-term disability due to back pain as a global health problem, variation in frequency related to demographics, direct and indirect costs, and predictors of chronic disability.

Narrative review with 119 citations focused on magnitute of back pain as a global health problem, variation in frequency related to demographics, direct and indirect costs, and predictors of chronic disability.

Narrative review of credible guidelines related to long-term disability due to back pain as a global health problem.
Measurement of Disability


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STUDY DESIGN: The Oswestry Disability Index (ODI) and SF-36 Physical Function Domain (SF-36 PF), and PROMIS Pain Interference (PI) and PROMIS Physical Function (PF) were administered to a prospective cohort of 1,992 patients complaining of back or leg pain, visiting a university-based spine clinic. All questionnaires were collected electronically, using a tablet computer. OBJECTIVE: The aim of this study was to compare the psychometric properties of the PROMIS PF CAT with the ODI and SF-36 Physical Function Domain in the same patient population. SUMMARY OF BACKGROUND DATA: Evidence-based decision-making is improved by using high-quality patient-reported outcome measures. Prior studies have revealed the shortcomings of the ODI and SF-36, commonly used in spine patients. The PROMIS Network has developed measures with excellent psychometric properties. The Physical Function domain, delivered by Computerized Adaptive Testing (PF CAT), performs well in the spine patient population, though to date direct comparisons with common measures have not been performed. METHODS: Standard Rasch analysis was performed to directly compare the psychometrics of the PF CAT, ODI, and SF-36 PF. Spearman correlations were computed to examine the correlations of the three instruments. Time required for administration was also recorded. RESULTS: One thousand six hundred four patients were administered all assessments. The time required to answer all items in the PF CAT, ODI, and SF-36 PF was 44, 169, and 98 seconds. The ceiling and floor effects were acceptable for the PF CAT (0.87, 0.86), while the ceiling effects were marginal and floor effects were quite poor for the ODI (6.50% and 44.24%) and SF-36 PF (1.97% and 23.65%), all instruments significantly correlated with each other. CONCLUSION: The PROMIS PF CAT outperforms the ODI and SF-36 PF in the spine patient population and is highly correlated. It has better coverage, while taking less time to administer with fewer questions to answer.

Measurement of Disability


http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4938742/

STUDY DESIGN: A prospective and retrospective cross-sectional cohort analysis. OBJECTIVE: The aim of this study was to show that Patient-Reported Outcomes Measurement Information System (PROMIS) computer adaptive testing (CAT) assessments for physical function and pain interference can be efficiently collected in a standard office visit and to evaluate these scores with scores from previously validated Oswestry Disability Index (ODI) and Neck Disability Index (NDI) data. MATERIALS AND METHODS: Data on surgical outcomes are highly variable, and substantial debate continues regarding the role and value of spine surgery. The routine collection of patient-reported outcomes instruments may inform this debate. Traditionally, the inefficiency associated with collecting standard validated instruments has been a barrier to routine use in outpatient clinics. The study utilized CAT instruments available through PROMIS and correlated these with the results obtained using "gold standard" legacy measurements. METHODS: All measurements were collected as a routine clinical visit. The ODI and NDI assessments were considered as "gold standard" comparisons for patient-reported outcomes. RESULTS: PROMIS CAT instruments required 4.5 ± 1.8 questions, with a median of 4.0. Convergent validity was demonstrated between PROMIS CAT and ODI/NDI (r = 0.67; p < 0.001) and between PROMIS CAT and PROMIS 36-item SF (r = 0.79; p < 0.001). CONCLUSION: Routine collection of physical function outcome measures in clinical practice offers the ability to inform and improve patient care. We have shown that several PROMIS CAT instruments can be efficiently administered during routine clinical visits. The moderate to strong correlations found validate the utility of computer adaptive testing when compared with the gold standard "legacy" measures.

Measurement of Disability


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Objectives: To examine the relationship between the Patient Reported Outcome Measurement Information System (PROMIS) Pain Interference (PI) and PROMIS Physical Function (PF) scores in patients with spinal pain at a university spine center. Design: Retrospective analysis of prospectively collected patient-reported outcome data at a university spine clinic. Patients who had undergone surgery at our institution were invited to complete the PROMIS Physical Function and Pain Interference scores. Linear regression analysis predicted relationship properties. Statistical significance was set at p < 0.05. Results: A total of 1,962 participants completed an assessment, with 1,923 completing the PROMIS PF (97.9%) and PI (97.7%) CATs. Participants' mean age was 52.8 years (range 18-94 years, SD = 15.5 years). Correlation analysis of the PROMIS PI with the PROMIS PI showed a Pearson correlation value of 0.757 (p < 0.001). There was a strong linear relationship with a high negative correlation between PROMIS PI and PI CAT. The PI CAT performed better than the SF36 PI scale (p = 0.727, F = 0.001). Conclusions: For patients with pain from spinal origin, there is a strong negative correlation between self-reported physical function and pain interference related to physical, social, and mental health. The predictive relationship of function from pain scores supports the PROMIS PI being used as an important adjunct measure of physical function in patients with spine pain.

Satellite: Computerized Adaptive Testing (CAT) assessments for physical function and pain interference can be efficiently collected in a standard office visit and to evaluate these scores with scores from previously validated Oswestry Disability Index (ODI) and Neck Disability Index (NDI) providing evidence of convergent validity for use in patients with spine pathology. SUMMARY OF BACKGROUND DATA: Evidence-based decision-making is improved by using high-quality patient-reported outcome measures. Prior studies have revealed the shortcomings of the ODI and SF-36, commonly used in spine patients. The PROMIS Network has developed measures with excellent psychometric properties. The Physical Function domain, delivered by Computerized Adaptive Testing (PF CAT), performs well in the spine patient population, though to date direct comparisons with common measures have not been performed. METHODS: Standard Rasch analysis was performed to directly compare the psychometrics of the PI CAT, ODI, and SF-36 PI. Spearman correlations were computed to examine the correlations of the three instruments. Time required for administration was also recorded. RESULTS: One thousand six hundred four patients were administered all assessments. The time required to answer all items in the PI CAT, ODI, and SF-36 PI was 44, 169, and 98 seconds. The ceiling and floor effects were acceptable for the PI CAT (0.87, 0.86), while the ceiling effects were marginal and floor effects were quite poor for the ODI (6.50% and 44.24%) and SF-36 PI (1.97% and 23.65%), all instruments significantly correlated with each other. CONCLUSION: The PROMIS PI CAT outperforms the ODI and SF-36 PI in the spine patient population and is highly correlated. It has better coverage, while taking less time to administer with fewer questions to answer.
Single institution study of a small number of patients with back pain in which function scores were correlated with pain scores. Limited statistical analysis. Questionnaire is rapidly completed by patients and in wide use.

"To our knowledge, the validated version was less robust than for some other patient-reported outcomes measures."
**Measurement of Disability**

Weiss RL, Njoroge JB, Newick IA, Szpirer KL, Cola D. Development of physical and mental health summary scores from the patient-reported outcome measurement information system (PROMIS) global items. Qual Life Res. 2010 Sep;19(7):743-6. PMID: 19843805

BACKGROUND: The use of global health items permits an efficient way of gathering general perceptions of health. These items provide useful summary information about health and are predictive of health care utilization and subsequent mortality. METHODS: Analyses of 10 self-reported global health items obtained from an internet survey as part of the Patient-Reported Outcome Measurement Information System (PROMIS) project. We derived summary scores from the global health items. We estimated the correlations of the summary scores with the EQ-5D index score and the PROMIS physical function, pain, fatigue, emotional distress, and social health domain scores. RESULTS: Exploratory and confirmatory factor analyses supported a two factor model. Global physical health (GPH; 4 items on overall physical health, physical function, pain, and fatigue) and global mental health (GMH; 4 items on quality of life, mental health, satisfaction with social activities, and emotional problems) scales were created. The scales had internal consistency reliability coefficients of 0.81 and 0.86, respectively. GPH correlated more strongly with the EQ-5D than did GMH (r = 0.74 vs. 0.56). GPM correlated most strongly with pain impact (r = 0.73) whereas GMH correlated most strongly with depressive symptoms (r = 0.71). CONCLUSIONS: Two dimensions representing physical and mental health underlie the global health items in PROMIS. These global health scales can be used to efficiently summarize physical and mental health in patient-reported outcome studies.

**Measurement of Disability**


OBJECTIVE: To evaluate the validity of the Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function measures using longitudinal data collected in six chronic health conditions. STUDY DESIGN AND SETTING: Individuals with rheumatoid arthritis (RA), major depressive disorder (MDD), back pain, chronic obstructive pulmonary disease (COPD), chronic heart failure (CHF), and cancer completed the PROMIS Physical Function computerized adaptive test or fixed-length short form at baseline and at the end of clinically relevant follow-up intervals. Anchor items were also administered to assess change in physical function and general health. Linear mixed-effects models and standardized response means were estimated at baseline and follow-up. RESULTS: A total of 1,415 individuals participated (COPD = 121, CHF = 57, back pain = 218, MDD = 196, RA = 521; cancer = 302). The PROMIS Physical Function scores improved significantly for treatment of CHF and back pain patients but not for patients with MDD or COPD. Most of the patient subsamples that reported improvement or worsening on the anchors showed a corresponding positive or negative change in PROMIS Physical Function. CONCLUSION: This study provides evidence that the PROMIS Physical Function measures are sensitive to change in intervention studies where physical function is expected to change and to distinguish among different clinical samples. The results inform the estimation of meaningful change, enabling comparative effectiveness research.

**Measurement of Disability**


BACKGROUND: Despite the overall effectiveness of total hip arthroplasty (THA), a subset of patients remains dissatisfied with their results because of persistent pain or functional limitations. It is therefore important to develop tools capable of identifying patients at risk for poor outcomes before surgery. QUESTIONS/PURPOSES: The purpose of this study was to use preoperative patient-reported outcome measures (PROMs) to predict which patients undergoing THA are most likely to experience a clinically meaningful change in functional outcome 1 year after surgery. METHODS: A retrospective cohort study design was used to evaluate preoperative and 1 year postoperative SF-12 v2 version 2 (SF12v2) and Hip Disability and Osteoarthritis Outcome Score (HOOS) items from 137 selected patients who underwent primary unilateral THA. Minimum clinically important differences (MCIDs) were calculated using a distribution-based method. A receiver operating characteristic (ROC) curve analysis was used to calculate threshold values, defined as the levels at which substantial changes occurred, and their predictive ability. MCID values for HOOS and SF12v2 physical component summary (PCS) scores were calculated to be 5.1 and 4.6, respectively. We analyzed the effect of SF12v2 mental component summary (MCS) scores, which measure mental and emotional health, on SF12v2 PCS and HOOS threshold values. RESULTS: Threshold values for preoperative HOOS and PCS scores were a maximum of 51.0 (area under the curve [AUC], 0.74; p < 0.001) and 32.5 (AUC, 0.62; p < 0.001), respectively. As preoperative mental and emotional health improved, which was reflected by a higher MCS score, HOOS and PCS threshold values also increased. When preoperative mental and emotional health were taken into account, both HOOS and PCS threshold values' predictive abilities improved (AUCs increased to 0.77 and 0.69, respectively). CONCLUSION: We identified PROMS threshold values that predict clinically meaningful improvements in functional outcomes after THA. Patients with a higher level of preoperative function, as suggested by HOOS and PCS scores above the defined threshold values, are less likely to obtain meaningful improvement after THA. Lower preoperative mental and emotional health decreases the likelihood of achieving a clinically meaningful improvement in function after THA. The results of this study may be used to facilitate discussion between physicians and patients regarding the expected benefit after THA and to support the development of patient-based informed decision making tool. For example, despite significant disease, patients with high preoperative function, as measured by PROMS scores, may choose to delay surgery given the low likelihood of experiencing a meaningful improvement postoperatively. Similarly, patients with totally low...
Measurement of Disability

NICE guideline [NG59]. Low back pain and sciatica in over 16s: assessment and management. Published date: November 2016.

A prospective cohort study from University of Utah of 2226 patients (mean age of 61.61, 61.6% White, 89.7% Caucasian) with unspecified proportion of patients lost to follow-up aimed at establishing minimum clinically important differences following total hip or total knee arthroplasty performed for a variety of conditions. Follow-up period ranged from <3 to ≥6 months. "The median MCID value in the range was similar to the mean change score for each measure and was 7.0 for the PF CAT, 18.0 for the HOOS JR, and 15.1 for the KOOS JR." Authors acknowledge absence of a standardized approach to measuring MCID and wider ranges with different populations and methodologies and emphasize "individual value judgements are necessarily to apply MCIDs to treatment planning and guiding patient expectations of treatment change."

-- Study with substantial methodological limitations. offers an approach and cautions in applying MCIDs to clinical decision making and prediction.

Noninvasive treatments for low back pain and sciatica

Invasive treatments for low back pain and sciatica

Nonsurgical treatment

Lower scores indicating less severe symptoms) at 6 weeks, 3 months, 6 months, 1 year, and 2 years.

The median MCID value in the range was similar to the mean change score for each measure and was 7.0 for the PF CAT, 18.0 for the HOOS JR, and 15.1 for the KOOS JR. This is the first comprehensive study providing a wide range of MCIDs for the PROMIS® PF, HOOS JR, and KOOS JR in orthopaedic patients with joint disorders.

Establishing minimum clinically important differences following total hip or total knee arthroplasty performed for a variety of conditions. Follow-up period ranged from <3 to ≥6 months. "The median MCID value in the range was similar to the mean change score for each measure and was 7.0 for the PF CAT, 18.0 for the HOOS JR, and 15.1 for the KOOS JR." Authors acknowledge absence of a standardized approach to measuring MCID and wider ranges with different populations and methodologies and emphasize "individual value judgements are necessarily to apply MCIDs to treatment planning and guiding patient expectations of treatment change."

-- Study with substantial methodological limitations. offers an approach and cautions in applying MCIDs to clinical decision making and prediction.

Invasive treatments for low back pain and sciatica

Non-invasive treatments for low back pain and sciatica

Nonsurgical treatment versus surgery


sinktrial.org (report number: NCT00000409 [ClinicalTrials.gov]).

degenerative spondylolsthesis and spinal stenosis treated surgically showed substantially greater improvement in pain and function during a period of 2 years than patients treated nonsurgically. (ClinicalTrials.gov number, NCT00000409). ClinicalTrials.gov.

BACKGROUND: The management of degenerative spondylolisthesis associated with spinal stenosis remains controversial. Surgery is widely used and has recently been shown to be more effective than nonoperative treatment when the results were followed for over two years. Questions remain regarding the long-term effects of surgery. This study compares surgical treatment with that of nonoperative treatment. METHODS: Surgical candidates from thirteen centers with symptoms of at least twelve weeks duration as well as confirmatory imaging showing degenerative spondylolisthesis with spinal stenosis were offered enrollment in a randomized cohort or observational cohort. Treatment consisted of standard decompressive laminectomy versus surgery or nonoperative care. Primary outcome measures were the Short Form-36 (SF-36) bodily pain and physical function scores and the modified Oswestry Disability Index at six weeks, three months, six months, and yearly up to four years. RESULTS: In the randomized cohort (360 patients enrolled), 40% of those randomized to nonoperative care received lumbar surgery in the four years whereas 56% of those randomized to receive lumbar surgery received it whereas 33% of those who chose nonoperative care ultimately received surgery. The intent-to-treat analysis of the randomized cohort, which was limited by nonadherence to the assigned treatment, showed no significant differences in treatment outcomes between the operative and nonoperative groups at three or four years. An as-treated analysis combining the randomized and observational cohorts that adjusted for potential confounders demonstrated that the clinically relevant advantages of surgery that had previously been reported through two years were maintained for four years, with treatment effects of 15.3 (95% confidence interval, 11.1-19.5) for bodily pain, 18.9 (95% confidence interval, 14.8-22.9) for physical function, and -14.3 (95% confidence interval, -17.5 to -11.1) for the Oswestry Disability Index. Early advantages (at two years) of surgical treatment in terms of the secondary outcomes of back and leg symptoms, overall satisfaction with current symptoms, and self-rated progress were also maintained at four years. CONCLUSIONS: Compared with patients who are treated nonoperatively, patients in whom degenerative spondylolisthesis and associated spinal stenosis are treated surgically maintain substantially greater pain relief and improvement in function for four years.

This study cohort was limited to patients with spinal stenosis without spondylolisthesis (studied separately in Weinstein 2007 and 2008), with neuromuscular claudication and/or radicular leg pain of at least 12 weeks duration, treated with standard decompressive laminectomy. As in the related trial (SPORT) of degenerative spondylolisthesis noted above, there was an RCT component and an observational cohort component. The RCT portion had substantial crossover. Results were based on an “as-treated” analysis combining randomized and observational cohorts. Patients treated surgically had less pain, improved physical function and improved Oswestry scores.

Early results of laparoscopic decompression with or without fusion demonstrated the surgical care at four years. Analysis of observational cohort showed benefit from surgery. (see Weinstein 2007 for the 2-year results)
BACKGROUND AND PURPOSE: The aim of this study was to examine 5 commonly used questionnaires for assessing disability in people with low back pain. The modified Oswestry Disability Questionnaire, the Quebec Back Pain Disability Scale, the Roland-Morris Disability Questionnaire, the Waddell Disability Index, and the physical health scales of the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) were compared in patients undergoing physical therapy for low back pain. SUBJECTS AND METHODS: Patients with low back pain completed the questionnaire during initial consultation with a physical therapist and again 6 weeks later (n=100). Test-retest reliability was examined for a group of 47 subjects who were classified as "unchanged" and a subgroup of 16 subjects who were self-rated as "about the same." Responsiveness was compared using standardized response means, receiver operating characteristic curve, and the proportions of subjects who changed by at least as much as the minimum detectable change (MDC: 90% confidence interval of the standard error for repeated measures). Scale width was judged as adequate if no more than 15% of the subjects had initial scores at the upper or lower end of the scale that were insufficient to allow change to be reliably detected. RESULTS: Intraclass correlation coefficients (2,1) calculated to measure reliability for the subjects who were classified as "unchanged" and those who were self-rated as "about the same" were greater than 0.90 for the Oswestry and Quebec questionnaires and the SF-36 Physical Functioning scale and less than 0.60 for the Waddell and Roland-Morris questionnaires and the SF-36 Role-Physical and Bodily Pain scales. None of the scales were more responsive than any other. DISCUSSION AND CONCLUSION: Measurements obtained with the modified Oswestry Disability Questionnaire, the SF-36 Physical Functioning scale, and the Quebec Back Pain Disability Scale were the most reliable and had sufficient width to reliably detect improvement or worsening in most subjects. The reliability of measurements obtained with the Waddell Disability Index was moderate, but the scale appeared to be insufficient to recommend it for clinical application. The Roland-Morris Disability Questionnaire and the Role Limitations-Physical and Bodily Pain scales of the SF-36 appeared to lack sufficient reliability and scale width for clinical application.

Abstract: OBJECT: It is not known whether adding fusion to lumbar decompression is necessary for all patients undergoing surgery for degenerative lumbar spondylolisthesis with symptomatic stenosis. Screening spinal radiographic traits that might predict delayed instability following decompression surgery might guide clinical decision making regarding the utility of up-front fusion in patients with degenerative Grade I spondylolisthesis. METHODS: Patients with Grade I degenerative lumbar spondylolisthesis (3-14 mm) with symptomatic stenosis were prospectively enrolled from a single site between May 2002 and September 2009 and treated with decompression laminectomy without fusion. Patients with mechanical back pain or with gross motion (> 3 mm) on flexion-extension lumbar radiographs were excluded. The baseline radiographic variables measured included amount of spondylolisthesis, disc height, facet angle, motion at spondylolisthesis (flexion-extension), and sagittal station angle. Data were analyzed using multivariate forward selection stepwise logistic regression, Chi-square tests, Student t-test, and ANOVA. RESULTS: Forty patients were enrolled and treated with laminectomy without fusion, and all patients had complete radiographic data sets that were available for analysis. Reoperation was performed in 15 (37.5%) of 40 patients, with a mean follow-up duration of 3.6 years. Reoperation was performed for pain caused by instability at the index level in all 15 cases. Using multivariate stepwise logistic regression with a threshold value of 0.05, motion at spondylolisthesis, disc height, and facet angle were predictors of reoperation following surgery. Facet angle > 50° was associated with a 90% rate of reoperation, disc height > 6.5 mm was associated with a 45% rate of reoperation, and motion at spondylolisthesis > 1.25 mm was associated with a 54% rate of reoperation. Patients with all 3 risk factors for instability had a 75% rate of reoperation, whereas patients with no risk factors for instability had a 0% rate of reoperation (p = 0.14). CONCLUSIONS: Patients with motion at spondylolisthesis > 1.25 mm, disc height > 6.5 mm, and facet angle > 50° were more likely to experience instability following decompression surgery for Grade I lumbar spondylolisthesis. Identification of key risk factors for instability might improve patient selection for decompression without fusion surgery.

Validates minimum detectable change on ODI as 10.5-15 points. It supports minimum difference of 10.5 points or ODI to 80% certain that change has occurred.
Assessment of Lumbar Segmental Instability in Degenerative Lumbar Spondylolisthesis


PURPOSE: The term "segmental instability" of the lumbar spine is not clearly defined, especially as it relates to degenerative spondylolisthesis (DS) and rotational translation (RT). We investigated whether facet joint effusion on conventional supine MRI indicated increased abnormal mobility (IM) and RT. METHODS: 160 patients (110 female, 41 male, mean age 68.8 years, range 36-98) who had undergone decompression only or decompression with instrumented fusion for degenerative spondylolisthesis with different degrees of slippage and the spinal cord were identified prospectively from our spine surgery database. All had a preoperative upright X-ray in AP and lateral views as well as supine MRI. The imaging studies were assessed for the following parameters: percent of slippage, absolute value of facet joint effusion, facet angle, degree of facet degeneration and spinous canal central narrowing, disc height, presence of facet cysts and the presence of rotational translation in the AP X-ray. RESULTS: 40/150 patients showed no facet joint effusion, and in these the difference in the values for the % slip and supine X-ray and % slip on supine MRI was 0%. A further 22 patients also showed a difference 0%, but had some fluid in the joints (0.49 ± 0.38 mm). In 108 patients, the difference in the % slip measured on X-ray and on MRI was 1% (mean 10.6%, range 4-29%). and was associated with a mean facet effusion size of 2.15 ± 0.05 mm. The extent of effusion correlated significantly with the relative slipage difference between standing and supine positions (r = 0.64, p < 0.001), and the extent of the left/right difference in effusion was associated with the presence of rotational translation (RT 1.1 ± 0.8 mm vs. RT 0.1 ± 0.3 mm, p < 0.001). CONCLUSIONS: Facet joint effusion is clearly correlated with spontaneous reduction of the extent of slippage in the supine position compared to the upright position. Also, the greater the difference in right and left facet effusion, the higher the likelihood of having a RT. Future studies should assess whether analysis of facet joint effusion measured on routine MRI can help in decision-making regarding the optimal surgical treatment to be applied (decompression alone or combined with fusion).

A retrospective cohort study assessing the correlation of preoperative facet joint effusion with % slip on upright X-ray and supine MRI. Study established a correlation between effusion and slippage of vertebra. Authors acknowledge the difficulty in achieving consistent imaging planes. Did not include functional measures pre or post operatively.

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Supports the conclusion that sensitivity of conventional imaging techniques may be sub-optimal and additional or alternative imaging studies may help in decision making with regard to surgery. Reviewers judged the findings to reflect an "intermediate outcome" rather than a "patient oriented outcome."
Nonsurgical Treatment - Physiatrist consultation


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STUDY DESIGN: Prospective trial with insurance database and survey. OBJECTIVE: This study was developed to determine whether an insurer rule requiring physiatrist consultation before nonsurgical surgical consultation would affect surgery referrals and surgery rates. SUMMARY OF BACKGROUND DATA: Spine surgery rates are highly variable by region and increasing without evidence of a concordant decrease in the burden of disease. Efforts to curb misuse of surgery have not shown large changes, especially across different provider groups. As nonsurgical spine experts, physiatrists might provide patients with a different perspective on treatment options. METHODS: In 2007, the insurer required patients with nonurgent spine surgical consultations in a geographic region to first have a single visit with a physiatrist, who received extra compensation for the assessment. Surgical consultation and surgical rates results were compared between 2006-2007 and 2008-2010. RESULTS: Telephone surveys of patients evaluated by physiatrists provided response rates of 92% or greater. Rates of surgical referrals were reduced by 70% and rates of surgical consultation decreased at all regional hospitals and all surgical groups, there were substantial shifts in market share. CONCLUSION: Mandatory physiatrist consultation prior to surgical consultation resulted in decreased surgical rates and continued patient satisfaction across a large region.

Prospective cohort study with historical controls sponsored by a health plan and including 6 health systems that compared rates of spine surgery with or without a consultation with a physiatrist. A physiatry consultation was required to qualify as a Center of Excellence. When physiatry consultation was required the rates of spine surgery decreased, "...screen" referrals to physiatrists did not result in a substantial increase in electrodiagnostic testing or spinal imaging (p > 0.05) between the 2 time periods. 79% of patients were satisfied or very satisfied with a physiatrist. Surgical rates decreased with a mandatory consultation with a physiatrist while maintaining satisfactory patient satisfaction.

Nonsurgical Treatment - Early PT


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BACKGROUND: Low back pain (LBP) is common in primary care. Guidelines recommend delaying referrals for physical therapy. OBJECTIVE: To evaluate whether early physical therapy (manipulation and exercise) is more effective than usual care in improving disability for patients with LBP fitting a decision rule. DESIGN, SETTING, PARTICIPANTS: Randomized trial with 220 participants recruited between March 2011 and November 2012. Participants with no LBP treatment in the past 6 months, aged 18 through 65 years (mean age 47 years [SD, 10.3]), an Oswestry Disability Index (ODI) score of 20 or higher, a symptom duration less than 60 days, and no symptoms detailed in the knee in the past 72 hours were enrolled following a primary care visit. INTERVENTIONS: All participants received education. Early physical therapy (n = 110) consisted of 4 physical therapy sessions, Usual care (n = 112) included no additional interventions during the first 6 weeks. MAJOR OUTCOMES AND MEASURES: Primary outcome was change in the ODI score (range: 0-100); higher scores indicate greater disability, minimum clinically important difference, 6 points) at 3 months. Secondary outcomes include changes in the ODI score at 4-week and 1-year follow-up, and change in pain intensity, Pain Catastrophizing Scale (PCS) score, fear-avoidance beliefs, quality of life, patient-reported success, and heath care utilization at 4-week, 4 months, and 1-year follow-up. RESULTS: One year follow-up was completed by 202 participants (91.5%). Using analysis of covariance, early physical therapy showed improvement relative to usual care in disability after 3 months (mean ODI score: early physical therapy group, 34.2 [95% CI, 28.0 to 40.4]; usual care group, 40.9 [95% CI, 38.6 to 43.2]) at baseline to 6.6 [95% CI, 4.7 to 8.5] at 3 months; usual care group, 40.9 [95% CI, 38.6 to 43.2] at baseline to 9.8 [95% CI, 4.7 to 14.9] at 3 months; between-group difference, -6.8 [95% CI, -10.3 to -3.3] at 6 months; -6.8 [95% CI, -10.3 to -3.3] at 12 months; -6.8 [95% CI, -10.3 to -3.3] at 24 months; -6.8 [95% CI, -10.3 to -3.3] at 36 months; -6.8 [95% CI, -10.3 to -3.3] at 48 months; -6.8 [95% CI, -10.3 to -3.3] at 60 months). A significant difference was found between the groups for the ODI score after 6 weeks (between-group difference, -5.2 [95% CI, 0.8 to -9.6] at 6 weeks; -6.8 [95% CI, -10.3 to -3.3] at 12 weeks; -6.8 [95% CI, -10.3 to -3.3] at 24 weeks; -6.8 [95% CI, -10.3 to -3.3] at 36 weeks; -6.8 [95% CI, -10.3 to -3.3] at 48 weeks; -6.8 [95% CI, -10.3 to -3.3] at 60 weeks). + Data does not support value of early physical therapy in reducing impairment or healthcare utilization in patients with uncomplicated low back pain.

A randomized controlled trial of 220 patients with back pain and an ODI score of 20 or higher, symptom duration less than 16 days and without "red flag findings" that received four physical therapy sessions. Control group received educational education but no physical therapy. Outcomes included ODI, Pain Catastrophizing Scale, and healthcare utilization. Experimental group had statistically significant improvement in disability at 6 weeks. Our results did not reach minimum clinically important difference at 3 months. No difference in healthcare utilization at 4 weeks, 4 months, and 1 year. 16 of 128 patient in the control group had "off treatment" therapeutic interventions.

> Recommended source with robust evidence appraisal.

* A recommended non-surgical care interventions are education, self-management, physical activity, structured exercise programs, cognitive behavioral therapy, combined physical and psychology programs, facilitating return to usual function, NAIDs [with PPI], and manual therapy. Recommendation stratified with STarT Back tool at first visit.
I. C. Nonsurgical Treatment


EM Tier 2 Source

Abstract: We aimed to evaluate the evidence on the effectiveness of surgical interventions for a number of conditions resulting in low back pain (LBP) or spine-related limiting leg pain. We searched the Cochrane databases and PubMed to June 2012. We included systematic reviews and randomized controlled trials (RCTs) on degenerative disc disease (DDD), herniated disc, spondylolisthesis and spinal stenosis due to degenerative osteoarthritis. We included comparisons between surgery and conservative care and between different techniques. The quality of the systematic reviews was evaluated using assessment of multiple systematic reviews (AMSTAR). Twenty systematic reviews were included which covered the following diagnoses: disc herniation (n = 9), spondylolisthesis (n = 2), spinal stenosis (n = 2), DDD (n = 6) and combinations (n = 2). For most of the comparisons, no significant and/or clinically relevant differences between interventions were identified. In general, surgery is only indicated for relief of leg pain in clear indications such as disc herniation, spondylolisthesis or spinal stenosis. Copyright 2013. Published by Elsevier Ltd.

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I. C. Nonsurgical Treatment


BACKGROUND CONTEXT: The evidence-based clinical guideline on the diagnosis and treatment of degenerative lumbar spinal stenosis by the North American Spine Society (NASS) provides evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of degenerative lumbar spinal stenosis. The guideline is intended to reflect contemporary treatment concepts for symptomatic degenerative lumbar spinal stenosis as reflected in the highest quality clinical literature available on this subject as of July 2010.

CONCLUSIONS: The goals of the guideline recommendations are to assist in delivering optimum efficacious treatment and functional recovery from this spinal disorder. PURPOSE: Provide an evidence-based educational tool to assist spine care providers in improving quality and efficiency of care delivered to patients with degenerative lumbar spinal stenosis.

STUDY DESIGN: Systematic review and evidence-based clinical guideline.

METHODS: This report is from the Degenerative Lumbar Spinal Stenosis Work Group of the NASS’s Evidence-Based Clinical Guideline Development Committee. The work group consisted of multidisciplinary spine care specialists trained in the principles of evidence-based analysis. The original guideline, published in 2006, was carefully reviewed. A literature search addressing each question and using a specific search protocol was performed on English language references found in MEDLINE, EMBASE (Drugs and Pharmacology), and four additional evidence-based, databases to identify articles published since the search performed for the original guideline. The relevant literature was then independently rated by a minimum of three physician reviewers using the NASS-adopted standardized levels of evidence. An evidentiary table was created for each of the questions. Final recommendations to answer each clinical question were arrived at via work group discussion, and grades were assigned to the recommendations using standardized grades of recommendation. In the absence of levels I to IV evidence, work group consensus statements have been developed using a modified normal group technique, and these statements are clearly identified as such in the guideline. Systematic reviews were assessed addressing issues of natural history, diagnosis, and treatment of degenerative lumbar spinal stenosis. The answers summarized in this document. The respective recommendations were graded by the strength of the supporting literature that was stratified by levels of evidence.

RESULTS: Sixteen key clinical questions were assessed, recommendations using standardized grades of recommendation. In the absence of Levels I to IV evidence, work group consensus statements have been developed using a modified normal group technique, and these statements are clearly identified as such in the guideline. Systematic reviews were assessed addressing issues of natural history, diagnosis, and treatment of degenerative lumbar spinal stenosis. The answers summarized in this document. The respective recommendations were graded by the strength of the supporting literature that was stratified by levels of evidence.

CONCLUSIONS: The guideline reflects contemporary treatment concepts for symptomatic degenerative lumbar spinal stenosis as reflected in the highest quality clinical literature available on this subject as of July 2010. The guideline is reflects current treatment concepts for symptomatic degenerative lumbar spinal stenosis as reflected in the highest quality clinical literature available on this subject as of July 2010.

Reasonably well-detailed methods section re: evidence grading and guideline development. Cohort is patients with spinal stenosis in 18 years and older with a chief complaint of neurogenic claudication without diastolic stenosis. Among the recommendations are:

- Level 1 recommendation that validated criteria should be used for interpreting imaging studies.
- Work Group consensus that physical therapy is an option for patients with lumbar spinal stenosis, unsupervised, with reliable evidence.
- Level 3 recommendation for the use of lumbar scoliosis to increase walking distance and decrease pain in patients with lumbar spinal stenosis. Insufficient evidence to support use of traction, electrical stimulation, TENS, or acupuncture.
- Level 2 evidence that method / interventional treatment may provide improvement for 2-10 years.
- Level 3 recommendation that decompressive surgery may improve outcomes in patients with severe relief of lumbar spinal stenosis.
- Level 4 recommendation that decompression alone is suggested for patients with leg predominant symptoms without instability.

See Kramer article as possible updated edition of this document.

Evidence-based clinical guideline

- Provides an update to the NASS Guideline, 2011, cited below.

Kramer article as possible updated edition of this document.

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I. C. Nonsurgical Treatment


The guideline reflects contemporary treatment concepts for symptomatic degenerative lumbar spinal stenosis as reflected in the highest quality clinical literature available on the subject as of July 2010.


Cognitive-behavioral therapy, or progressive relaxation (weak recommendation, moderate-quality evidence).

Interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation (weak recommendation, moderate-quality evidence).

DEGENERATION OF THE LUMBAR SPINE IS DESCRIBED AS LUMBAR SPONDYLOSIS OR DEGENERATIVE DISC DISEASE AND MAY LEAD TO SPINAL STENOSIS (NARROWING OF THE SPINAL CANAL), VERTEBRAL INSTABILITY AND/OR ENLARGEMENT, WHICH MAY BE ASSOCIATED WITH BACK PAIN AND/OR LEG SYMPTOMS. THIS REVIEW CONSIDERS THE AVAILABLE EVIDENCE ON THE PROCEDURE OF SPINAL DECOMPRESSION (WIDENING THE SPINAL CANAL OR LAMINECTOMY), NERVE ROOT DECOMPRESSION (OF ONE OR MORE INDIVIDUAL NERVES) AND FUSION OF ADJACENT VERTEBRAE.

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I/C Nonsurgical Treatment


Abstract: Background: Regular paracetamol is the recommended first-line analgesic for acute low-back pain; however, no high-quality evidence supports this recommendation. We aimed to assess the efficacy of paracetamol taken regularly or as needed to improve time to recovery from pain, compared with placebo, in patients with low back pain. Methods: We did a multicentre, double-dummy, randomised, placebo-controlled trial at 235 primary care centres in Sydney, Australia, from Nov 1, 2009, to March 5, 2013. We randomly allocated patients with acute low-back pain to a 1:1 ratio to receive up to 4 weeks of regular doses of paracetamol (three times per day; equivalent to 3900 mg paracetamol per day), or placebo. Randomisation was done according to a centralised randomisation schedule prepared by a researcher who was not involved in patient recruitment or data collection. Patients and staff at all sites were masked to treatment allocation. All participants received best-evidence advice and were followed up for 3 months. The primary outcome was time until recovery from low-back pain, with recovery defined as a pain score of 0 (on a 0–10 pain scale) sustained for 7 consecutive days. All data were analysed by intention to treat. This study is registered with the Australian and New Zealand Clinical Trial Registry, number ACTRN12608000462091. Findings: 593 patients were assigned to the regular group (354 analysed), 549 were assigned to the as-needed group (546 analysed), and 553 were assigned to the placebo group (547 analysed). Median time to recovery was 17 days (IQR 14–19) in the regular group, 17 days (15–20) in the as-needed group, and 16 days (14–20) in the placebo group (regular vs placebo hazard ratio 0·96, 95% CI 0·87–1·06; as needed vs placebo 1·05, 0·92–1·19; regular vs as-needed 1·05, 0·92–1·19). We recorded no difference between treatment groups for time to recovery (adjusted p=0·76). Adherence to regular tablets (median tablets consumed per participant per day of treatment 4·0 [IQR 1·6–5·8]) in the regular group, 3·9 [1·5–5·6] in the as-needed group, and 4·0 [1·5–5·7] in the placebo group), and number of participants reporting taking regular paracetamol (99 [18·7%] in the as-needed group, and 99 [18·5%] in the placebo group), and number of participants reporting taking regular paracetamol (99 [18·5%] in the regular group, 99 [18·7%] in the as-needed group, and 99 [18·5%] in the placebo group) were similar between groups.

Interpretation: Our findings suggest that regular or as-needed dosing with paracetamol does not affect recovery time compared with placebo in low-back pain, and question the universal endorsement of paracetamol as standard practice. Funding: National Health and Medical Research Council of Australia. Clinical trial number ISRCTN37113406.


Study was by intention to treat. This study is registered, number ISRCTN13114364. FINDINGS: 851 patients were allocated patients with acute low-back pain in a 1:1:1 ratio to receive up to 4 weeks of regular doses of paracetamol (three times per day; equivalent to 3900 mg paracetamol per day), or placebo. Paracetamol was found to be no better than placebo in reducing time to recovery from pain. However, no high-quality evidence supports this recommendation. We aimed to assess the efficacy of paracetamol taken regularly or as needed to improve time to recovery from pain, compared with placebo, in patients with low back pain. Methods: We did a multicentre, double-dummy, randomised, placebo-controlled trial at 235 primary care centres in Sydney, Australia, from Nov 1, 2009, to March 5, 2013. We randomly allocated patients with acute low-back pain to a 1:1 ratio to receive up to 4 weeks of regular doses of paracetamol (three times per day; equivalent to 3900 mg paracetamol per day), as-needed doses of paracetamol (taken when needed for pain relief; maximum 4000 mg paracetamol per day), or placebo. Randomisation was done according to a centralised randomisation schedule prepared by a researcher who was not involved in patient recruitment or data collection. Patients and staff at all sites were masked to treatment allocation. All participants received best-evidence advice and were followed up for 3 months. The primary outcome was time until recovery from low-back pain, with recovery defined as a pain score of 0 (on a 0–10 pain scale) sustained for 7 consecutive days. All data were analysed by intention to treat. This study is registered with the Australian and New Zealand Clinical Trial Registry, number ACTRN12608000462091. Findings: 593 patients were assigned to the regular group (354 analysed), 549 were assigned to the as-needed group (546 analysed), and 553 were assigned to the placebo group (547 analysed). Median time to recovery was 17 days (IQR 14–19) in the regular group, 17 days (15–20) in the as-needed group, and 16 days (14–20) in the placebo group (regular vs placebo hazard ratio 0.96, 95% CI 0.87–1.06; as needed vs placebo 1.05, 0.92–1.19; regular vs as-needed 1.05, 0.92–1.19). We recorded no difference between treatment groups for time to recovery (adjusted p=0.76). Adherence to regular tablets (median tablets consumed per participant per day of treatment 4.0 [IQR 1.6–5.8]) in the regular group, 3.9 [1.5–5.6] in the as-needed group, and 4.0 [1.5–5.7] in the placebo group), and number of participants reporting taking regular paracetamol (99 [18.7%] in the as-needed group, and 99 [18.5%] in the placebo group), and number of participants reporting taking regular paracetamol (99 [18.5%] in the regular group, 99 [18.7%] in the as-needed group, and 99 [18.5%] in the placebo group) were similar between groups.

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Non-surgical Treatment


Objectives. To compare the effectiveness of lumbar instrumented fusion with cognitive intervention and exercises in patients with chronic low back pain and disc degeneration. Summary of Background Data. To the authors' best knowledge, only one randomized study has evaluated the effectiveness of lumbar fusion. The Swedish Lumbar Spine Study reported that lumbar fusion was better than continuing physiotherapy and care by the family physician. Patients and Methods. Forty-six patients aged 18–65 years with low back pain lasting longer than 1 year and evidence of disc degeneration at L4–L5 and/or L5–S1 at radiographic examination were randomized to either lumbar fusion with posterior transpedicular screws and postoperative physiotherapy, or cognitive intervention and exercises. The cognitive intervention consisted of a lecture to give the patient an understanding that ordinary physical activity would not harm the disc and a recommendation to use the back and bend it. This was reinforced by three daily physical exercise sessions for 3 weeks. The main outcome measure was the Oswestry Disability Index. Results. At the 1 year follow-up, 97% of the patients, including 4 patients who had either not attended treatment or dropped out, were examined. The Oswestry Disability Index was significantly reduced from 45 to 25 after surgery, compared with 42 to 30 after cognitive intervention and exercises. The mean difference between groups was 13.1 (95% CI 7.5–10.4). Improvements in pain, use of analgesics, emotional distress, life satisfaction, and return to work were not different. Fear-avoidance beliefs and fingertip flexion distance were reduced more after nonoperative treatment, and lower limb pain was reduced more after surgery. The success rate according to an independent observer was 75% after surgery and 76% after cognitive intervention and exercises. Conclusions. Lumbar fusion offers no greater benefit than non-surgical care for patients with low back pain and disc degeneration. Complication rate of 18% (95% CI 12–24) included wound infection, bleeding, venous thrombosis and dural tear.

Non-surgical Treatment; Measure of treatment response


The study established the criterion validity, test–retest reliability and responsiveness of the CareConnections Functional Index. The CareConnections Functional Index (CCI) is comprised of four body-region specific subscales, measuring functional ability. Reference standard included the Neck Disability Index; Modified Oswestry Disability Index; Quick Disabilities of the Arm, Shoulder and Hand and the Lower Extremity Functional Scale. One hundred subjects in the primary region were enrolled. Subject’s rated their perceived improvement based on the 15-point Global Rating of Change questionnaire. Minimal clinically important differences (MCID) were calculated using various response characteristic curve. Test–retest reliability coefficients were good to excellent. Validity correlations with the reference standard measures were acceptable (r=0.77, 0.73, 0.56, 0.56) for subscales. MCID for the cervical subscale (C7 points, shoulder/shoulder points, upper extremity sub2 points and lower extremity sub2 points). The results of this study support the use of the CCI as an outcome measurement tool for clinical decision making in patients with chronic neck pain. The CCI is a valid tool for clinical decision making in patients with chronic neck pain. The CCI is a valid tool for clinical decision making in patients with chronic neck pain.

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Nonsurgical Treatment; Cognitive Behavioral Therapy

OBJECTIVES: To assess the clinical effectiveness of surgical stabilization (spinal fusion) compared with intensive rehabilitation for patients with chronic low back pain. DESIGN: Multicentre randomised controlled trial (REHABILITATION of chronic low back pain). The intervention arm of the trial was a community-based psychosocial intervention programme based on principles of cognitive-behavioral therapy. INTERVENTION: Lumbar spine fusion or an intensive rehabilitation programme consisting of weight training, hydrotherapy, and core stability strengthening. OUTCOME MEASURES: The primary outcome was the Oswestry disability index and the shuttle walking test measured at baseline and two years after randomisation. The SF-36 instrument was used as a secondary outcome measure. RESULTS: 176 participants were assigned to surgery and 175 to rehabilitation. 286 (81%) provided follow-up data at 24 months. The mean Oswestry disability index changed favourably from 44.5 (SD 14.6) to 36.4 (SD 21.3) in the surgery group and from 44.0 (SD 14.2) to 36.0 (SD 21.6) in the rehabilitation group. The estimated mean difference between the groups was 4.1 (95% confidence interval 1.3 to 6.9; p = 0.004) in favour of surgery. No significant differences between the treatment groups were observed in the shuttle walking test or any of the other outcome measures. CONCLUSION: Both treatment groups reported reductions in disability during two years of follow-up, possibly unrelated to the interventions. The statistical difference between treatment groups in one of the two primary outcome measures was marginal and only just reached the predefined minimal clinical difference, and the potential risk and additional cost of surgery also need to be considered. No clear evidence emerged that primary spinal fusion surgery was any more beneficial than intensive rehabilitation.

2/B

Lumbar spine fusion or an intensive rehabilitation programme consisting of weight training, hydrotherapy, and core stability strengthening.

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3/B

Lumbar spine fusion or an intensive rehabilitation programme consisting of weight training, hydrotherapy, and core stability strengthening.

OBJECTIVE: To assess the clinical effectiveness of surgical stabilization (spinal fusion) compared with intensive rehabilitation for patients with chronic low back pain. DESIGN: Multicentre randomised controlled trial (REHABILITATION of chronic low back pain). The intervention arm of the trial was a community-based psychosocial intervention programme based on principles of cognitive-behavioral therapy. INTERVENTION: Lumbar spine fusion or an intensive rehabilitation programme consisting of weight training, hydrotherapy, and core stability strengthening. OUTCOME MEASURES: The primary outcome was the Oswestry disability index and the shuttle walking test measured at baseline and two years after randomisation. The SF-36 instrument was used as a secondary outcome measure. RESULTS: 176 participants were assigned to surgery and 175 to rehabilitation. 286 (81%) provided follow-up data at 24 months. The mean Oswestry disability index changed favourably from 44.5 (SD 14.6) to 36.4 (SD 21.3) in the surgery group and from 44.0 (SD 14.2) to 36.0 (SD 21.6) in the rehabilitation group. The estimated mean difference between the groups was 4.1 (95% confidence interval 1.3 to 6.9; p = 0.004) in favour of surgery. No significant differences between the treatment groups were observed in the shuttle walking test or any of the other outcome measures. CONCLUSION: Both treatment groups reported reductions in disability during two years of follow-up, possibly unrelated to the interventions. The statistical difference between treatment groups in one of the two primary outcome measures was marginal and only just reached the predefined minimal clinical difference, and the potential risk and additional cost of surgery also need to be considered. No clear evidence emerged that primary spinal fusion surgery was any more beneficial than intensive rehabilitation.

4/B

Lumbar spine fusion or an intensive rehabilitation programme consisting of weight training, hydrotherapy, and core stability strengthening.

OBJECTIVE: To assess the clinical effectiveness of surgical stabilization (spinal fusion) compared with intensive rehabilitation for patients with chronic low back pain. DESIGN: Multicentre randomised controlled trial (REHABILITATION of chronic low back pain). The intervention arm of the trial was a community-based psychosocial intervention programme based on principles of cognitive-behavioral therapy. INTERVENTION: Lumbar spine fusion or an intensive rehabilitation programme consisting of weight training, hydrotherapy, and core stability strengthening. OUTCOME MEASURES: The primary outcome was the Oswestry disability index and the shuttle walking test measured at baseline and two years after randomisation. The SF-36 instrument was used as a secondary outcome measure. RESULTS: 176 participants were assigned to surgery and 175 to rehabilitation. 286 (81%) provided follow-up data at 24 months. The mean Oswestry disability index changed favourably from 44.5 (SD 14.6) to 36.4 (SD 21.3) in the surgery group and from 44.0 (SD 14.2) to 36.0 (SD 21.6) in the rehabilitation group. The estimated mean difference between the groups was 4.1 (95% confidence interval 1.3 to 6.9; p = 0.004) in favour of surgery. No significant differences between the treatment groups were observed in the shuttle walking test or any of the other outcome measures. CONCLUSION: Both treatment groups reported reductions in disability during two years of follow-up, possibly unrelated to the interventions. The statistical difference between treatment groups in one of the two primary outcome measures was marginal and only just reached the predefined minimal clinical difference, and the potential risk and additional cost of surgery also need to be considered. No clear evidence emerged that primary spinal fusion surgery was any more beneficial than intensive rehabilitation.
BACKGROUND: Chiropractors commonly use a combination of interventions to treat people with low-back pain (LBP). OBJECTIVES: To determine the effects of combined chiropractic interventions (that is, a combination of therapies, other than spinal manipulation alone) on pain, disability, back-related function, overall improvement, and patient satisfaction in adults with LBP, aged 18 and older. SEARCH STRATEGY: We searched The Cochrane Back Review Group Trials Register (May 2008), CENTRAL (The Cochrane Library 2008, Issue 2), and EMBASE (from January 1966), EMBASE (from January 1966), CRHWEB, (from January 1964), MANTIS (from inception) and the Index to Chiropractic Literature (from Inception) to May 2008. We also screened references of identified articles and contacted chiropractic researchers. SELECTION CRITERIA: All randomised trials comparing the use of combined chiropractic interventions (rather than spinal manipulation alone) with no treatment or other therapies. DATA COLLECTION AND ANALYSIS: At least two review authors selected studies, assessed the risk of bias, and extracted the data using standardised forms. Both descriptive synthesis and meta-analyses were performed. MAIN RESULTS: We included 12 studies involving 2887 participants with LBP. Three studies had low risk of bias. Included studies evaluated a range of chiropractic procedures in a variety of sub-populations of people with LBP. No trials were located of combined chiropractic interventions compared to no treatment. For acute and subacute LBP, chiropractic interventions improved short- and medium-term pain (SMD -0.21 (95% CI -0.46 to -0.00) and MD -0.08 (95% CI -0.38 to 0.11)) compared to other treatments, but there was no significant difference in long-term pain (MD -0.41 (95% CI -1.07 to 0.25)). Short-term improvement in disability was greater in the chiropractic group compared to other therapies (SMD -0.36 (95% CI -0.73 to 0.02)). However, the effect was small and all studies contributing to these results had high risk of bias. There was no difference in medium- and long-term disability. No difference was demonstrated for combined chiropractic interventions for chronic LBP and for studies that had a mixed population of LBP. AUTHORS' CONCLUSIONS: Combined chiropractic interventions slightly improved pain and disability in the short-term and pain in the medium-term for acute and subacute LBP. However, there is currently no evidence that supports or refutes these interventions provide a clinically meaningful difference for pain or disability in people with LBP when compared to other interventions. Future research is very likely to change the estimate of effect and our confidence in the estimate. A meta analysis addressing chiropractic treatments for low back pain

BACKGROUND: Many therapies exist for the treatment of low-back pain including spinal manipulative therapy (SMT), which is a worldwide, extensively practiced intervention. OBJECTIVES: To assess the effects of SMT for chronic low-back pain. SEARCH STRATEGY: An updated search was conducted by an experienced librarian to June 2009 for randomised controlled trials (RCTs) in CENTRAL (The Cochrane Library 2009, Issue 2), MEDLINE, EMBASE, CRHWEB, PEDro, and the Index to Chiropractic Literature. SELECTION CRITERIA: RCTs which examined the effectiveness of spinal manipulation or mobilisation in adults with chronic low-back pain were included. No restrictions were placed on the setting or type of pain; studies which exclusively examined sciatica were excluded. The primary outcomes were pain, functional status and perceived recovery. Secondary outcomes were return to work and quality of life. DATA COLLECTION AND ANALYSIS: Two review authors independently conducted the study selection, risk of bias assessment and data extraction. GRADE was used to assess the quality of the evidence. Sensitivity analyses and investigation of heterogeneity were performed, where possible, for the meta-analyses. MAIN RESULTS: We included 36 RCTs (total participants = 6070), nine of which had a low risk of bias. Approximately two thirds of the included studies (n = 16) were not evaluated in the previous review. In general, there is high quality evidence that SMT has a small, statistically significant but not clinically relevant, short-term effect on pain relief (MD -4.16, 95% CI -6.97 to -1.36) and functional status (SMD -0.22, 95% CI -0.43 to -0.02) compared to other interventions. Sensitivity analyses confirmed the robustness of these findings. There is varying quality of evidence (ranging from low to high) that SMT has a statistically significant short-term effect on pain relief and functional status when added to another intervention. There is very low-quality evidence that SMT is not statistically significantly more effective than inert interventions or sham SMT for short-term pain relief or functional status. Data were particularly sparse for recovery, return to work, quality of life, and costs of care. No serious complications were observed with SMT. AUTHORS' CONCLUSIONS: High quality evidence suggests that there is no clinically relevant difference between SMT and other interventions for reducing pain and improving function in patients with chronic low-back pain. Determining cost-effectiveness of care has high priority. Further research is likely to have an important impact on our confidence in the estimate of effect in relation to inert interventions and sham SMT, and data related to recovery.

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Nonosurgical Treatment; Acupuncture


BACKGROUND: Acupuncture is a popular complementary and alternative treatment for chronic back pain. Recent European trials suggest similar short-term benefits from real and sham acupuncture needling. This trial addresses the importance of needle placement and skin penetration in eliciting acupuncture effects for patients with chronic low back pain.

METHODS: A total of 438 adults with chronic mechanical low back pain were randomized to individualized acupuncture, standardized acupuncture, simulated acupuncture, or usual care. Ten treatments were provided over 7 weeks by experienced acupuncturists. The primary outcomes were back-related dysfunctions (Roland-Morris Disability Questionnaire score; range, 0-22) and symptom bothersomeness (0-5 scale). Outcomes were assessed at baseline and after 8, 26, and 52 weeks. RESULTS: In 48 weeks, mean dysfunctions scores for the individualized, standardized, and simulated acupuncture groups improved by 4.4, 4.5, and 4.4 points, respectively, compared with 2.1 points for those receiving usual care (P < .001). Participants receiving real or simulated acupuncture were more likely than those receiving usual care to experience clinically meaningful improvements on the dysfunctions scale (30% vs 8% vs 9%, respectively, P < .001). Symptoms improved by 3.6 to 3.9 points in the treatment groups compared with 0.7 points in the usual care group (P < .001). After 1 year, participants in the treatment groups were more likely than those receiving usual care to experience clinically meaningful improvements: in dysfunctions (59% vs 60% vs 58%, respectively, P > .05) but not in symptoms (P > .05).

CONCLUSIONS: Although acupuncture was found effective for chronic low back pain, tailoring needling sites to each patient and penetration of the skin appear to be unimportant in eliciting therapeutic benefits. These findings raise questions about acupuncture’s purported mechanisms of action. It remains unclear whether acupuncture or our simulated method of acupuncture provide physiologically important stimulation or represent placebo or nonspecific effects.

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<th>Cycle 1: Epidural Injections</th>
<th>Cycle 2: Fitness for Surgery</th>
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<td><strong>Objective:</strong> Lumbar epidural steroid injections (LESIs) are performed for both diagnostic and therapeutic purposes for a variety of indications, including low-back pain, the leading cause of disability and expense due to work-related conditions in the US. The steroid agent used in epidural injections is reported to relieve nerve root inflammation, local ischemia, and resultant pain, but the injection may also have an adverse impact on spinal surgery performed thereafter. In particular, the possibility that preoperative epidural injections may increase the risk of surgical site infection after lumbar spinal fusion has been reported but has not been studied in depth. The goal of the present study was to use a large national insurance database to evaluate the association of preoperative LESIs with surgical site infection after lumbar spinal fusion. <strong>Method:</strong> A nationwide insurance database of patient records was used for this retrospective analysis. Current Procedure Terminology codes were used to query the database for patients who had undergone 2-level or 3-level lumbar posterior spine fusion procedures. The rate of postoperative infection after 1- or 2-level posterior spinal fusion was analyzed. <strong>Results:</strong> There were 30,683 patients over 65 years of age in the study. The rate of postoperative infection in patients receiving epidural steroid injection within 3 months prior to lumbar fusion surgery was 1.8% (341 of 18,852 patients). The infection risk increased in patients who received LESI within 1 month (OR 2.4, p &lt; 0.0001) or 1-3 months (OR 1.4, p = 0.0002) prior to surgery compared with controls. The infection risk was significantly greater than controls in patients who underwent lumbar fusion more than 3 months after LESI. <strong>Conclusion:</strong> Lumbar spinal fusion performed within 3 months after LESI may be associated with an increased rate of postoperative infection. This association was not found when lumbar fusion was performed more than 3 months after LESI.</td>
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Background context: Prior studies on the impact of obesity on spine surgery outcomes have focused mostly on lumbar fusions, do not examine lumbar disc outcomes or decompressions, and have shown mixed results regarding complications. Differences in sample sizes and body mass index (BMI) thresholds for the definition of obese versus comparison cohorts could account for the inconsistencies in the literature. Purpose: The purpose of the study was to analyze whether different degrees of obesity influence the complication rates in patients undergoing lumbar spine surgery. Study design/setting: This was a retrospective cohort analysis of prospectively collected data using the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database from 2005 to 2010. Patient sample: Patients in the de-identified, risk-adjusted, and multi-institutional ACS NSQIP database undergoing lumbar anterior fusion, posterior fusion, transitional lumbar interbody fusion/posterior lumbar interbody fusion (TLIF/PF), decompression, or decompression were included. Outcome measures: Primary outcome measures were 30-day postoperative complications, including pulmonary embolism and deep venous thrombosis, death, system-specific complications (wound, pulmonary, urinary, central nervous system, and cardiac), reoperative complications, and having one or more complications overall. Secondary outcomes were time spent in the operating room, blood transfusions, length of stay, and reoperation within 30 days. Methods: Patients undergoing lumbar anterior fusion, posterior fusion, TLIF/PF, decompression, or decompression in the ACS NSQIP (2005 to 2010) were categorized into four BMI groups: Nonobese (18.5–29.9 kg/m2), Obese I (30–34.9 kg/m2), Obese II (35–39.9 kg/m2), and Obese III (greater than or equal to 40 kg/m2). Obese I to III patients were compared with patients in the nonobese category using chi-square test and analysis of variance. Multivariate binary logistic regression models were used to adjust for preoperative risk factors. Results: Data were available for 10,387 patients undergoing lumbar surgery. Of these, 6% underwent anterior fusion, 17% posterior fusion, 6% TLIF/PF, 40% discectomy, and 30% decompression. Among all patients, 26% were in the Obese I group, 11.5% Obese II, and 6.9% Obese III. On multivariate analysis, Obese I and III had a significantly increased risk of urinary complications, and Obese II and III patients had a significantly increased risk of wound complications. Only Obese III patients, however, had a statistically increased risk of having increased time spent in the operating room, an extended length of stay, mortality complications, and having one or more complications (all p < 0.05). Conclusions: Patients with high BMI appear to have higher complication rates after lumbar surgery than patients who are nonobese. However, the impact of obesity on surgical complications was not associated with worse surgical outcomes (in terms of treatment success). Obesity does not affect the clinical outcome of operative treatment of SpS. There are higher rates of infection and reoperation and less improvement from baseline in the SF-36 physical function score in obese patients after surgery for DS. Nonoperative treatment may not be as effective in obese patients with SpS or DS.

Study Design: Retrospective subgroup analysis of prospectively collected data according to treatment received. Objective: The purpose of this study was to determine whether obesity affects treatment outcomes for lumbar stenosis (SpS) and degenerative spondylolisthesis (DS). Summary of Published Data: Obesity is thought to be associated with increased complications and potentially less favorable outcomes after the treatment of degenerative conditions of the lumbar spine. This, however, remains a matter of debate in the existing literature. METHODS: An as-treated analysis was performed on patients enrolled in the Spine Patient Outcomes Research Trial for the treatment of SpS or DS. A comparison was made between patients with a body mass index (BMI) of less than 30 (“nonobese,” n = 373 SpS and 379 DS) and those with a BMI of 30 or more (“obese,” n = 261 SpS and 225 DS). Baseline patient characteristics, intraoperative data, and complications were documented. Primary and secondary outcomes were measured at baseline and regular follow-up time intervals up to 4 years. The difference in improvement over baseline between surgical and nonsurgical treatment (i.e., treatment effect) was determined at each follow-up interval for the obese and nonobese groups. RESULTS: At 4-year follow-up, operative and nonoperative treatment provided improvement in all primary outcome measures over baseline to patients with BMI of less than 30 and 30 or more. For patients with SpS, there were no differences in the surgical complication or reoperation rates between groups. Patients with DS with BMI of 30 or more had a higher postoperative infection rate (5% vs. 1%, p < 0.01) and twice the reoperation rate at 4-year follow-up (20% vs. 10%, P < 0.01) than those with BMI of less than 30. At 4 years, surgical treatment of SpS and DS were equally effective in both BMI groups in terms of the primary outcome measures, with the exception that obese patients with DS had less improvement from baseline in the 36-Item Short Form Health Survey (SF-36) physical function score than nonobese patients (22.6 vs. 27.5, P = 0.027). With nonoperative treatment, patients with SpS with BMI of 30 or more did worse in regard to all 3 primary outcome measures, and patients with DS with BMI of 10 or more had similar SF-36 bodily pain scores but less improvement over baseline in the SF-36 physical function and Oswestry Disability Index scores. Treatment effects for SpS and DS were significant within each BMI group for all primary outcome measures in favor of surgery. Obese patients had a significantly greater treatment effect than nonobese patients with SpS (Oswestry Disability Index, P = 0.037) and DS (SF-36 PF, P = 0.046) largely due to the relatively poor outcome of nonoperative treatment in obese patients. Conclusion: Obesity does not affect the clinical outcome of

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BACKGROUND: Several countries are discussing new legislation regarding the ban on smoking in public places, and smoking history was self-reported and nonsmoking status was not confirmed biochemically.

OBJECTIVE: To determine whether an intervention with smoking cessation starting 4 weeks before general and orthopedic surgery would reduce the frequency of postoperative complications.

METHODS: From a study on lung cancer in the EPIC cohort, questionnaire information on smoking was collected at enrolment, and cotinine was measured in serum. Three statistical models were applied by using samples available in a cross-section design: (i) cotinine levels by categories combining smoking and SHS (n = 859); (ii) the overall comparison between smokers and nonexposed, with a marked (but not significant) difference among former-smokers. A one hour per day exposure to secondhand smoke that demonstrated that second smoke increased serum cotinine. No patient related outcomes were reported.

CONCLUSION: Smoking cessation prior to surgery reduces postoperative complications if smoking discontinued as late as four weeks prior to surgery. A retrospective cohort study of 311 patients, either smokers or nonsmokers, undergoing spinal fusion between 1992 and 1996 were compared with regard to rate of surgical nonunion. Smoking history was self-reported and nonsmoking status was not confirmed biochemically.

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METHODS: A retrospective cohort study of 351 patients, either smokers or nonsmokers, undergoing spinal fusion between 1992 and 1996 were compared with regard to rate of surgical nonunion. Smoking history was self-reported and nonsmoking status was not confirmed biochemically.

RESULTS: In this study, the nonunion rate was 14.2% for nonsmokers and 26.5% for patients who continued to smoke after surgery (P < 0.05). Patients who quit smoking after surgery for longer than 6 months had a nonunion rate of 17.1%. The nonunion rate was not significantly affected by either the quantity that a patient smoked before surgery or the duration of preoperative smoking abatement. Return-to-work was achieved in 93% of smokers and 91% of nonsmokers. A one hour per day exposure to secondhand smoke that demonstrated that second smoke increased serum cotinine. No patient related outcomes were reported.

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Imperial College London: University of London. This study retrospectively identified 357 patients who underwent a posterior instrumented fusion at either L4-L5 or L4-S1 between 1992 and 1996. Analysis of the medical record and follow-up telephone surveys were conducted. Clinical outcome and fusion status was analyzed in relation to preoperative and postoperative smoking parameters.

RESULTS: Among nonsmokers, passive smokers presented significant differences in cotinine compared with nonsmokers and 26.5% for patients who continued to smoke after surgery (P < 0.05). Patients who quit smoking after surgery for longer than 6 months had a nonunion rate of 17.1%. The nonunion rate was not significantly affected by either the quantity that a patient smoked before surgery or the duration of preoperative smoking abatement. Return-to-work was achieved in 93% of smokers and 91% of nonsmokers. A one hour per day exposure to secondhand smoke that demonstrated that second smoke increased serum cotinine. No patient related outcomes were reported.

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BACKGROUND: Patients with diabetes mellitus are at increased risk of postoperative complications. Data from randomised clinical trials and meta-analyses point to a potential benefit of intensive glycaemic control, with a decrease in infectious complications across a variety of surgical procedures. However, there is limited evidence concerning this question in patients with diabetes mellitus undergoing surgery.

OBJECTIVES: To assess the effects of perioperative glycaemic control for diabetic patients undergoing surgery.

SEARCH METHODS: Trials were obtained from searches of The Cochrane Library, MEDLINE, EMBASE, LILACS, CINAHL and ISIS (all up to February 2012).

DATA COLLECTION AND ANALYSIS: Two authors independently extracted data and assessed risk of bias. We summarised studies using meta-analysis or descriptive methods. MAIN RESULTS: Twelve trials randomised 694 diabetic participants to intensive control and 709 diabetic participants to conventional glycaemic control. The duration of the intervention ranged from just the duration of the surgical procedure up to 90 days. The number of participants ranged from 13 to 421, and the mean age was 64 years. Comparison of intensive with conventional glycaemic control demonstrated the following results for our predefined primary outcomes: 9 trials included randomized controlled clinical trials that preselected different targets of perioperative glycaemic control (intensive versus conventional or standard care).

OUTCOME MEASURES: Primary outcomes were infectious complications, including pneumonia, wound infection, urinary tract infection, or sepsis. Bivariate analysis was used first to determine the association of each independent variable (age, race, diabetic treatment, American Society of Anesthesiologists classification, Activities of Daily Living assessment, elective vs emergent procedure, wound classification, operation length, and HbA(1c) levels) with outcome. Factors significant at P<0.05 were used in a multivariable logistic regression model. RESULTS: In the multivariable model, age, American Society of Anesthesiologists class, operation length, wound class, and HbA(1c) levels were significantly associated with postoperative infections. Emergent/urgent cases and dependence in Activities of Daily Living were significant in bivariate analysis but failed to reach statistical significance in the multivariable model. An HbA(1c) level of less than 7% was significantly associated with decreased infectious complications with an adjusted odds ratio of 2.13 (95% confidence interval, 1.23-3.70) and P value of 0.007. CONCLUSION: Good preoperative glycaemic control (HbA(1c) levels <7%) is associated with decreased postoperative infectious complications, including pneumonia, wound infection, urinary tract infection, or sepsis. Bivariate analysis was used first to determine the association of each independent variable (age, race, diabetic treatment, American Society of Anesthesiologists classification, Activities of Daily Living assessment, elective vs emergent procedure, wound classification, operation length, and HbA(1c) levels) with outcome. Factors significant at P<0.05 were used in a multivariable logistic regression model. RESULTS: In the multivariable model, age, American Society of Anesthesiologists class, operation length, wound class, and HbA(1c) levels were significantly associated with postoperative infections. Emergent/urgent cases and dependence in Activities of Daily Living were significant in bivariate analysis but failed to reach statistical significance in the multivariable model. An HbA(1c) level of less than 7% was significantly associated with decreased infectious complications with an adjusted odds ratio of 2.13 (95% confidence interval, 1.23-3.70) and P value of 0.007. CONCLUSION: Good preoperative glycaemic control (HbA(1c) levels <7%) is associated with decreased postoperative infectious complications across a variety of surgical procedures.
Glycemic Control

SUMMARY OF BACKGROUND DATA: Diabetes mellitus (DM) is a prevalent disease of glucose dysregulation that has been demonstrated to increase morbidity and mortality after surgery. However, there is limited understanding of whether glycemic control influences surgical outcomes in patients with DM undergoing lumbar spine procedures for degenerative conditions.

METHODS: The Nationwide Inpatient Sample was analyzed from 2002 to 2011. Hospitalizations were isolated on the basis of International Classification of Diseases, Ninth Revision, Clinical Modification, procedural codes for lumbar spine surgery and diagnosis codes for degenerative conditions of the lumbar spine. Patients were then classified into 3 cohorts: controlled diabetic, uncontrolled diabetic, and nondiabetic. Patient demographic data, intraoperative complications, and hospitalization outcomes were determined for each cohort. RESULTS: A total of 603,289 (15.7%) controlled diabetic patients and 16,057 (0.75%) uncontrolled diabetic patients underwent degenerative lumbar spine surgery from 2002 to 2011. Relative to nondiabetic patients, controlled diabetic patients had significantly increased odds of cardiac complications, deep venous thrombosis, and postoperative mortality. In addition, uncontrolled diabetic patients also had an increased mean length of stay (approximately, 3.5 d), greater costs ($7,548), and a greater risk of inpatient mortality (odds ratio=9.0, 95% confidence interval=3.2-24.8). Controlled diabetic patients also had increased odds of specific complications such as cardiac complications, deep venous thrombosis, and postoperative mortality when compared with nondiabetic patients, but not nearly to the same magnitude as uncontrolled diabetic patients.

CONCLUSIONS: Suboptimal glycemic control in diabetic patients undergoing degenerative lumbar spine surgery leads to increased risk of acute complications and poor outcomes. Patients with uncontrolled DM, or poor glucose control, may benefit from improving glycemic control prior to surgery.

STUDY DESIGN: Retrospective database analysis.

OBJECTIVES: To assess the effect glycemic control has on perioperative mortality and mortality in patients undergoing elective degenerative lumbar spine surgery.

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BACKGROUND: Unhealthy alcohol use is prevalent but under-diagnosed in primary care settings. OBJECTIVE: To evaluate, in primary care, a single-item screening test for unhealthy alcohol use recommended by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). DESIGN: Cross-sectional study. PARTICIPANTS: Adult English-speaking patients recruited from primary care waiting rooms. MEASUREMENTS: Participants were asked the single screening question, "How many times in the past year have you had 5 or more drinks in a day?", where 5 is for men and 4 for women, and a response of 1 or greater (corrected) is considered positive. Unhealthy alcohol use was defined as the presence of an alcohol use disorder, as determined by a standardized diagnostic interview, or risky consumption, as determined using a validated 30-day calendar method. MAIN RESULTS: Of 364 eligible primary care patients, 268 (73%) completed the interview. The single-question screen was 82.8% sensitive (95% confidence interval [CI] 72.1-88.5%) and 7.2% specific (95% CI 3.7-11.6%) for the detection of unhealthy alcohol use. It was slightly more sensitive (87.7%, 95% CI 72.7-95.2%) but was less specific (34.6%, 95% CI 30.8-38.3%) for the detection of a current alcohol use disorder. Test characteristics were similar to that of a commonly used three-item screen, and were affected very little by subject demographic characteristics. CONCLUSIONS: The single questioning recommended by the NIAAA accurately identified unhealthy alcohol use in this sample of primary care patients. These findings support the use of this brief screen in primary care.

A retrospective cohort study of 622 patients with diabetes and A1C measurements within 90 days of surgery. Study did not include patients undergoing orthopedic or spine surgery. Length of stay was compared among groups stratified for diabetes control and compared to patients without a diagnosis of diabetes. A1C values greater than 8% (and 6.5%) were associated with longer length of stay compared with controls. A new test used to identify patients with hemoglobin A1C levels greater than 8% 90 days after surgery have longer hospital stays.

A prospective study of patients treated in a primary care clinic that compared results of the "5 question test for unhealthy alcohol use" with a standardized diagnostic interview or a validated 30-day calendar method with measurements for sensitivity and specificity for the 5 question test. + Supports the use of a single question screen to identify unhealthy alcohol use.

Objective: Depression is the most prevalent affective disorder in the US, and patients with spinal deformity are at increased risk. Postoperative delirium has been associated with inferior surgical outcomes, including morbidity and mortality. The relationship between depression and postoperative delirium in patients undergoing spine surgery is relatively unknown. The aim of this study was to determine if depression is an independent risk factor for the development of postoperative delirium in patients undergoing decompression and fusion for deformity.

Methods: The medical records of 823 adult patients (age >18 years) undergoing elective spine surgery at a single major academic institution from 2005 through 2015 were reviewed. If these patients, 255 (27.6%) patients had been diagnosed with depression by a board-certified psychiatrist and constituted the Depression group; the remaining 668 patients constituted the No-Depression group. Patient demographics and comorbidities other than depression were similar in the 2 groups. In the Depression group, 85.1% of the patients were taking an antidepressant prior to surgery. There were no significant between-group differences in intraoperative variables and rates of complications other than delirium. Postoperative complication rates were also similar between the cohorts, including rates of urinary tract infection, fever, deep and superficial surgical site infection, pulmonary embolism, deep vein thrombosis, urinary retention, and rehospitalization of patients transferred to the intensive care unit. In total, 46 patients (7.10%) had an episode of postoperative delirium, with depressed patients experiencing approximately a 2-fold higher rate of delirium (10.59% vs 5.84%). In a multivariate logistic regression analysis, depression was an independent predictor of postoperative delirium, with depressed patients experiencing approximately a 2-fold higher rate of delirium (p = 0.01). CONCLUSIONS: The results of this study suggest that depression is an independent risk factor for postoperative delirium after elective spine surgery. Further studies are necessary to understand the effects of affective disorders on postoperative delirium, in hopes to better identify patients at risk.
Depression and Psychiatric disorders and major outcomes


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OBJECTIVES: The aim of the paper was to use a prospective, longitudinal, multicenter outcome registry of patients undergoing surgery for lumbar degenerative disease in order to assess the incidence and factors associated with 30-day reoperation and 90-day readmission. METHODS: Prospectively collected data from 9853 patients from the Quality and Outcomes Database (QOD) (formerly known as the NSQOD: National Neurosurgery Quality and Outcomes Database) lumbar spine registry were retrospectively analyzed. Multivariable logistic-regression analysis was performed to identify factors associated with 30-day reoperation and 90-day readmission after surgery for lumbar degenerative disease. A subgroup analysis of Medicare patients stratified by age (<65 and ≥65 years old) was also performed. Continuous variables were compared using unpaired t-tests, and proportions were compared using Fisher’s exact tests. RESULTS: There was a 2% reoperation rate within 30 days. Multivariable analysis revealed prolonged operative time during the index case was the only independent factor associated with 30-day reoperation. Other factors such as prescriptive diagnosis, body mass index (BMI), American Society of Anesthesiologists (ASA) class, diabetes, and use of spinal fusion were not associated with reoperations within 30 days. Medicare patients ≥65 years had a 30-day reoperation rate of 3.7%, whereas those ≥65 years had a 30-day reoperation rate of 2.2% (p = 0.020). Medicare beneficiaries younger than 65 years undergoing reoperation within 30 days were more likely to be white women (p = 0.008), have a higher BMI (p = 0.006), and have higher rates of depression (p = 0.006). The 90-day readmission rate was 6.3%. Multivariable analysis demonstrated that higher ASA class (OR 1.46, 95% CI 1.25–1.70) and history of depression (OR 1.27, 95% CI 1.04–1.54) were factors associated with increased 90-day reoperation. Medicare beneficiaries had a higher rate of 90-day readmissions compared with those who had private insurance (OR 1.43, 95% CI 1.17–1.70). Medicare patients ≥65 years of age were more likely to be readmitted within 90 days after their index surgery compared with those ≥65 years (OR 3.00, 95% CI 2.57–3.50) (p < 0.0001). Medicare patients ≥65 years of age had a significantly higher BMI (p < 0.001) and higher rates of depression (p < 0.0001). CONCLUSIONS: In this analysis of a large prospective, multicenter registry of patients undergoing lumbar degenerative surgery, multivariate analysis revealed that prolonged operative time was associated with 30-day reoperation. The authors found that factors associated with 90-day readmission included higher ASA class and a history of depression. The 90-day reoperation rates were higher for Medicare beneficiaries than for those who had private insurance. Medicare patients ≥65 years of age were more likely to undergo readmission within 90 days. A retrospective cohort study of prospectively consented national registry patients undergoing surgery for lumbar degenerative disease aimed at identifying “incidence and risk factors associated with 30-day reoperation and 90-day readmission.” Authors found that higher ASA class and depression were associated with increased 90-day readmission rates. Medicare beneficiaries had higher 90-day readmission rates. >> Supports the conclusion that 90-day readmissions were associated with higher ASA class and depression.


SUMMARY OF BACKGROUND DATA: Psychiatric comorbidity is a known risk factor for impaired health-related quality of life and poor long-term outcomes after spine surgery, yet little is known about its impact in the perioperative spine surgery setting.

METHODS: Using the National Hospital Discharge Survey database of patients undergoing either spinal fusion or laminectomy between 1990 and 2007, we identified and separated into groups with and without psychiatric comorbidities. Multivariable regression analysis was performed for each of the outcome variables.

RESULTS: Among 3900 and 2027, a total estimated number of 5,882,345 spinal fusions and laminectomies were performed. The prevalence of diagnosed depression, anxiety, and schizophrenia among the study population increased significantly over time. Depression, anxiety, schizophrenia, and dementia were associated with higher rates of in-hospital mortality. Depression, anxiety, and schizophrenia among the study population increased significantly over time. Depression, anxiety, schizophrenia, and dementia were associated with higher rates of in-hospital mortality. Depression, anxiety, and schizophrenia among the study population increased significantly over time. Depression, anxiety, schizophrenia, and dementia were associated with higher rates of in-hospital mortality. Depression, anxiety, schizophrenia, and dementia were associated with higher rates of in-hospital mortality. Depression, anxiety, schizophrenia, and dementia were associated with higher rates of in-hospital mortality. 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Depression, anxiety, schizophrenia, and dementia were associated with higher rates of in-hospital mortality. >> Supports the conclusion that patients with psychiatric conditions undergoing spine surgery have an increased rate of adverse events and a requirement for posthospitalization care.
II / A / 11 Depression screening

Wahlman M(1), Häkkinen A, Dekker J, Marttinen I, Vihtonen K, Neva MH.  The Screen for Osteoporosis

Schreiber JJ, Hughes AP, Taher F, Girardi FP.  An association can be found between

Sinikallio S(1), Aalto T, Airaksinen O, Herno A, Kröger H, Savolainen S, Turunen V,

PMID: 24482618


Eur Spine J. 2014 September 2014 - Bree Collaborative Lumbar Fusion Evidence Table

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Prospective cohort study from 2 Finnish hospitals with good follow-up. High prevalence of depression prior to lumbar fusion, improves following surgery, but remains above control population.

Prospective cohort study measuring prognosis for recovery in patients with preoperative depression. Patients remaining with persistent depression had less improvement following surgery. Small "n." Follow-up limited to three months. Type of surgery not specified and follow-up care not specified.

Supports value of presurgical detection of depression.

Screen for Osteoporosis


PMID: 23880907

The objective of this observational descriptive study was to investigate the effect of depression on short-term outcome after lumbar spinal stenosis (LSS) surgery. Surgery was performed on 95 patients with clinically and radiologically defined LSS, representing ordinary LSS patients treated at the secondary care level. They completed questionnaires before surgery and 3 months postoperatively. Depression was assessed with the 21-item Beck Depression Inventory (BDI). Physical functioning and pain were assessed with Oswestry disability index, Stucki Questionnaire, self-reported walking ability, visual analogue scale (VAS) and pain drawing. Preoperatively, 20% of the patients had depression. In logistic regression analyses, significant associations were seen between preoperative depression and postoperative high Oswestry disability and Stucki severity scores and high intensity of pain (VAS score). In subsequent analyses, the patients with continuous depression, measured with BDI (60% of the patients who had preoperative depression), showed fewer improvements in symptoms severity, disability score, pain intensity and walking capacity than the patients who did not experience depression at any phase. In those patients who remained depressed after surgery, according to BDI scores (35% of the patients with preoperative depression), the postoperative improvement was rather similar to the improvement seen in the normal mood group. In the surgical treatment of LSS, we recommend that the clinical practice should include an assessment of depression.

Cohen RA, Shuman LP, Peng S, Huh AT. An association can be found between household units and success of lumbar spinal fusion. HSJ. 2014 Feb;30(1):39-50. PMID: 24482610

PMID: 23880905

BACKGROUND: Measuring Hounsfield units (HUs) from computed tomography (CT) scans has recently been proposed as a tool for assessing vertebral bone quality, as it has been associated with bone mineral density, compression strength, and fracture risk. Vertebral bone quality is believed to be an important determinant of outcome and complication rates following spine surgery and potentially influences success of intervertebral fusion. QUESTION/PURPOSE: The purpose of this study was to investigate the association between HU on CT scans and fusion success in patients with lateral transpsoas surgery for lumbar interbody fusion (LIF).

METHODS: The CT scans of 28 patients with a combined 52 levels of stand-alone LIF were evaluated at a minimum of 12 weeks postoperatively. Coronal and sagittal images were evaluated for evidence of fusion, and HU values were collected from axial images. HU measurements were also taken from vertebral bodies proximal to the construct to evaluate global bone quality. RESULTS: Of the 52 LIF levels, 73% were assessed as fused and 27% were nonfused at the time of evaluation. The successful fusion levels had significantly higher HU measurements than the nonfused levels (203.3 vs. 139.8, p < 0.001). Patients with successful fusion constructs also had higher global bone density when vertebral bodies proximal to the construct were compared (133.7 vs. 107.5, p < 0.05). CONCLUSION: With the aging population and increasing prevalence of osteoporosis, preoperative assessment of bone quality prior to spinal fusion deserves special consideration. We found that a successful lumbar fusion was associated with patients with higher bone density, as assessed with HU, both globally and within the fusion construct, as compared to patients with CT evidence of nonfusion.

Retroprospective study of 28 patients with spinal fusion with subsequent measurement of bone quality as judged by CT scans (Hounsfield units). Patients with successful fusion had higher global bone density that patients with failed fusions. This was measured at minimum 12 weeks postoperatively.

In a low quality study due to small cohort and retrospective design. Relates successful lumbar fusion to higher bone density.

Depression screening

Gibbsler J, Hughes AP, Taher F, Girardi FP. An association can be found between household units and success of lumbar spinal fusion. HSJ. 2014 Feb;30(1):39-50. PMID: 24482610

PURPOSE: The aim of this study was to evaluate the prevalence of depressive symptoms and disability preoperatively, at 3 months and at 1 year after lumbar spine fusion surgery. METHODS: Data was extracted from a dedicated lumbar spine fusion registry, giving 232 patients (mean age 42 years, 158 females) who had undergone instrumented lumbar spine fusion. The frequency of depression symptoms and disability was evaluated using the Depression Scale (DFS) and Oswestry Disability Index (ODI). RESULTS: Depression symptoms were found in 36, 31 and 31% of the patients preoperatively, at 3 months and at 1 year after surgery, respectively. The mean DFS score decreased from 36.2 to 6.4 (p < 0.001) in patients who had depression symptoms preoperatively, and from 61.1 to 18.4 (p < 0.001) in those patients without preoperative depression symptoms. The mean ODI values preoperatively, at 3 months and at 1 year after surgery were 56, 30, and 22, respectively, in patients with preoperative depressive symptoms and 41, 23, and 20 in those patients without preoperative depressive symptoms. The differences between the groups were statistically significant at all time points (p < 0.01). CONCLUSIONS: One-third of our patients with chronic back pain undergoing spinal fusion had depression symptoms preoperatively. The prevalence of depressive symptoms decreased after surgery. Although disability remained higher in those patients who had received depressive symptoms preoperatively, disability did decrease significantly in both groups postoperatively. Thus, there is no need to exclude depressive patients from operation, but screening measures and appropriate treatment decisions throughout both preoperative and postoperative periods are encouraged.

Prospective cohort study of 28 Finnish hospitals with good follow-up. High prevalence of depression prior to lumbar fusion, improves following surgery, but remains above control population.

Supports the conclusion that depression is common in patients prior to and following lumbar fusion.

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Page 26 of 40 September 2014

METHODS: Patients with adjacent segment fractures after spinal fusion were identified from a prospectively collected patient database and matched 1:1 with nonfracture controls on the basis of age, sex, and fusion construct. Minimum follow-up was 6 months. Patients with metastatic bone disease other than osteoporosis or those taking medications known to negatively affect bone strength were excluded. HU assessment was done according to the previously published protocol using the preoperative computed tomography.

RESULTS: Twenty patients had complete imaging data and could be matched to nonfracture controls. The groups were well matched with respect to age, sex, body mass index, and number of levels fused. Following the standard surgical procedure, the fracture group had more anterior sagittal balance than the control group (107.9 vs. 91.1 cm). Analysis of HU values at the fracture level showed a significantly lower value in the fracture group. Due to the control (64.8 vs. 106.4, P < 0.001). Similarly, global assessment of HU across the thoracic and lumbar spines was significantly lower in the fracture group (125.9 vs. 171.9, P = 0.012).

CONCLUSIONS: HU was significantly lower both locally and globally in the fracture cohort. Because computed tomographic scan is frequently part of preoperative planning for spinal fusion, this information should be incorporated in preoperative planning. Studies to prospectively validate HU as a predictor of adjacent segment fracture risk and to assess the effect of increasing HU preoperatively with medications for osteoporosis are needed.

---

STUDY DESIGN: Retrospective case-control study.

OBJECTIVE: To determine the association of measurement with adjacent segment fractures after spinal fusion.

SUMMARY OF BACKGROUND DATA: Adjacent segment fractures are a potentially devastating complication after spinal fusion surgery in osteoporotic patient. Recently, a technique for assessing bone mineral density using dual-energy X-ray absorptiometry was described and correlated with both dual-energy X-ray absorptiometry-assessed bone mineral density and compressive strength in an osseous model.

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Observational study of 1,313 Korean patients undergoing spine surgery with bone density measured prior to surgery. Prevalence of osteoporosis in patients over 50 years was 14.5% for males and 55.2% for females. No outcome data reported. May not be applicable to non-Korean populations.

A retrospective cohort study of 20 patients with adjacent segment fractures after spinal fusion were compared to nonfracture controls with regard to reduced bone density as judged by computed tomography. Fracture patients had reduced bone density.
Liver function
(prothrombin, proteins, etc.)

Opioids


BACKGROUND: Patients with liver cirrhosis have high surgical risks due to malnutrition, impaired immunity, embolization, and encephalopathy. However, there is no information in English literature about the results of liver cirrhotic patients who underwent instrumented lumbar surgery. The purpose of this study is to report the perioperative complications, clinical outcomes and determine the surgical risk factors in cirrhotic patients.

METHODS: We retrospectively reviewed 29 patients with liver cirrhosis who underwent instrumented lumbar surgery between 1997 and 2009. The hepatic functional reserves of the patients were recorded according to the Child-Turcotte-Pugh scoring system. Besides, fourteen other variables and perioperative complications were also collected. To determine the risks, we divided the patients into two groups according to whether or not perioperative complications developed.

RESULTS: Of the 29 patients, 21 (72%) belonged to Child class A and 7 (24%) belonged to Child class B. Twelve patients developed one or more complications. Patients with Child class B had a significantly higher incidence of complications than those with Child class A (p = 0.011). In the Child class A group, patients with 6 or more had a significantly higher incidence of complications than those with 5 points (p = 0.05). A low level of albumin was significantly associated with higher risk, and a similar trend was also noted for the presence of ascites although statistical difference was not reached.

CONCLUSION: The study concludes that patients with liver cirrhosis who have undergone instrumented lumbar surgery carry a high risk of developing perioperative complications, especially in those with a Child-Turcotte-Pugh score of 6 or more.

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Nutritional status; Reduced serum albumin


BACKGROUND: Poor nutrition status is considered a risk factor for postoperative complications in the adult population. In elderly patients, who often have a poor nutrition status, this relationship has not been substantiated. Thus, the aim of this systematic review was to assess the merit of preoperative nutritional parameters used to predict postoperative outcome in elderly patients undergoing general surgery. METHODS: A systematic literature search of 10 consecutive years, 1998-2008, in PubMed, EMBASE, and Cochrane databases was performed. Search terms used were nutrition status, preoperative assessment, postoperative outcome, and surgery (hip or general), including their synonyms and MeSH terms. Limits used in the search were human studies, published in English, and age (65 years or older). Articles were screened using inclusion and exclusion criteria. All selected articles were checked on methodology and graded. RESULTS: Of 155 articles found, 15 were included. They showed profound heterogeneity in the parameters used for preoperative nutrition status and postoperative outcome. The only significant preoperative predictor of postoperative outcome in elderly general surgery patients was serum albumin and >= 10% weight loss in the previous 6 months. CONCLUSION: This systematic review revealed only 2 preoperative parameters to predict postoperative outcome in elderly general surgery patients: weight loss and serum albumin. Both are open to discussion in their use as a preoperative nutrition parameter. Nonetheless, serum albumin seems a reliable preoperative parameter to identify a patient at risk for nutrition deterioration and related complicated postoperative course.

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| Page 29 of 40 September 2014 - Bree Collaborative Lumbar Fusion Evidence Table |

| 10 | 9/4 | Shared Decision Making | Arterburn D. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. Health Affairs, 2012, Sep; 31(9): 2094-104. PMID: 22949460 | EM Tier 2 Source | http://elife.elsevier.com/home/citation/10.1016/j.spinee.2009.05.016 |

**Abstract:**

**A systematic review of 24 studies evaluating the effect of shared decision-making interventions on elective surgical care where choice for surgery could be changed by the patient.**

**Methods:**

We searched for English-language studies (January 1, 1990, to August 9, 2015) evaluating use of SDM in elective surgical care where choice for surgery could be changed by the patient. We included studies published in peer-reviewed, electronic databases and that focused on interventions for shared decision-making (SDM) that included a specific discussion about moderate average benefits, which appear to decrease over time. A summary of findings is presented including evidence-based practice, and reduce overuse of surgical care. Little is known, however, regarding the effects of SDM on elective surgical practice. The purpose of this systematic review is to synthesize findings of studies evaluating the use of SDM in elective surgical care where choice for surgery could be changed by the patient. The review evaluates the use of SDM in elective surgical care where choice for surgery could be changed by the patient. The review evaluates the use of SDM in elective surgical care where choice for surgery could be changed by the patient.

**Results:**

Among the studies, shared decision-making interventions resulted in a decrease in surgery (9 of 24), no difference (8 of 24), or an increase (1 of 24). SDM tended to improve decision-making, decision aids for some health conditions, for which treatment decisions are highly sensitive to both patients' and physicians' preferences, may reduce rates of elective surgery and lower costs.

- **Conclusion:**
  - Patients considering joint replacement surgery.
  - Supports use of shared decision-making to avoid surgery that the patient with otherwise.

**Recommendation:**

1. **Recommendation #5:** It is recommended that shared decision-making regarding surgery versus noninterdisciplinary nonsurgical therapy, and the fact that the majority of such patients who undergo surgery, do not experience an optimal outcome (defined as minimum or no pain, discontinuation of or occasional pain medication use, and return of high level function).

2. **Recommendation #7:** It is recommended that shared decision-making regarding surgery include a specific discussion about moderate average benefits, which appear to decrease over time in patients who undergo surgery.

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Shared Decision Making


EM Tier 1 source

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BACKGROUND: Decision aids are interventions that support patients by making their decisions explicit, providing information about options and assessed benefits/harms, and helping clarify convergence between decision and personal values.

EVIDENCE: To assess the effects of decision aids in people facing treatment or screening decisions.

SEARCH METHODS: Updated search (2012 to April 2015) in CENTRAL, EMBASE, PsycINFO, and grey literature. Inclusion: from 2004. EVIDENCE: We included published randomized controlled trials comparing decision aids to usual care or alternative interventions. For this update, we included studies comparing detailed versus simple decision aids. DATA COLLECTION AND ANALYSIS: Two reviewers independently screened citations for inclusion, extracted data, and assessed risk of bias. Primary outcomes, based on the International Patient Decision Aid Standards (IPDAS), were attributes related to the choice made and the decision-making process. Secondary outcomes were behavioral, health, and health system effects (the pooled results using mean differences (MDs) and risk ratios (RRs), applying a random-effects model. We conducted a subgroup analysis of studies that used the patient decision aid to prepare for the consultation and of those that used it in the consultation. We used GRADE to assess the strength of the evidence.

RESULTS: We included 105 studies involving 31,043 participants. This update added 18 studies and removed 28 previously included studies comparing detailed versus simple decision aids. During the ‘Risk of Bias’ assessment, we rated two items (selection reporting and blinding of participants/personnel) as mostly unclear due to inadequate reporting. Twelve of 105 studies were at high risk of bias. With regard to the attributes of the choice made, decision aids increased participants’ knowledge (MD -2.17/100; 95% confidence interval (CI) -3.32 to -1.03; 52 studies; N = 13,416; high-quality evidence), accuracy of risk perceptions (RR 2.10; 95% CI 1.64 to 2.66; 17 studies; N = 5096; moderate-quality evidence), and congruency between informed values and care choices (RR 2.16; 95% CI 1.49 to 3.18; 31 studies; N = 4069; low-quality evidence) compared to usual care. Regarding attributes related to the decision-making process and usual care, decision aids reduced decisional conflict related to feeling uninformed (MD -0.40/100; 95% CI -1.20 to 0.40; 27 studies; N = 5707; high-quality evidence), induced pressure about personal values (MD -0.10/100; 95% CI -0.04 to 0.50; 23 studies; N = 5718; low-quality evidence).

Conclusions: Decision aids for people facing health treatment or screening decisions improve participants’ knowledge and risk perceptions, congruency between their informed values and care choices, and decisional conflict related to feeling uninformed compared to usual care. Decision aids reduce pressure about personal values and increase the percentage of participants who report no decisional conflict related to feeling uninformed. There is high-quality evidence to support the use of decision aids in this context.

High quality guideline for “routine preoperative tests for elective surgery.”

Advance Directives


EM Tier 1 source

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High quality guideline for “routine preoperative tests for elective surgery.”

Washington State statute specifies offering the opportunity to the patient to designate a lay caregiver. Tasks include context information, necessary aftercare tasks, participation in discharge planning, instruction or training provided to the patient including medication management. Designated lay caregiver should be notified of patient’s discharge or transfer. Suggests more detailed review of bill to resolve questions or issues.

Advance Directives

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Prospective study of the effect of advance directives on end of the care. Suggests the use of advance directives to reduce the use of inappropriate and costly out-of-hospital care.

High quality guideline for “routine preoperative tests for elective surgery.”
II / C / 1 / a
Fitness for Surgery; antituberculosis treatment

Abstract: The rate of therapy of tuberculosis is remarkably low among American and nonAmerican patients with the human immunodeficiency virus (HIV). This poor result is attributable to several factors. NonAmerican patients, especially those who are refugees, are often unaware that they have tuberculosis. Moreover, whether patients are aware that they have tuberculosis, HIV infection may make it difficult for them to complete therapy. Furthermore, because many patients are infected with HIV-Tuberculosis, the diagnosis is often delayed, and therapy for tuberculosis is interrupted when the patient becomes aware of his or her HIV infection. The treatment of tuberculosis among HIV-infected patients is a public health problem, and the outcome of therapy depends on a variety of factors. Tuberculosis is currently the leading cause of death among patients with AIDS. 

Conclusion: Because tuberculosis is the leading cause of death among patients with AIDS, therapy is essential. Although therapy can be successfully completed among patients with HIV, the treatment of tuberculosis among HIV-infected patients is a public health problem. The outcome of therapy is influenced by a variety of factors. 

II / C / 1 / b
Cardiopulmonary Fitness

PMID: 25091544
http://www.onlinejacc.org/content/64/22/e77

Abstract not available

High quality society guideline with evidence appraisals

"The focus of this clinical practice guideline is the perioperative cardiovascular evaluation and management of the adult patient undergoing noncardiac surgery." 

II / C / 1 / c
Nasal culture; Chlorhexidine

PMID: 20054045

BACKGROUND: Nasal carriers of Staphylococcus aureus are at increased risk for health care-associated infections with this organism. Decolonization of nasal and extranasal sites on hospital admission may reduce this risk. METHODS: In a randomized, double-blind, placebo-controlled, multicenter trial, we assessed whether rapid identification of S. aureus nasal carriers by means of a real-time polymerase-chain-reaction (PCR) assay, followed by treatment with mupirocin nasal ointment and chlorhexidine soap, reduces the risk of hospital-associated S. aureus infection. RESULTS: From October 2005 through June 2007, a total of 6771 patients were screened on admission. A total of 1270 nasal swabs from 1251 patients were positive for S. aureus. We enrolled 817 of these patients in the intention-to-treat analysis, of whom 808 (88.1%) underwent a surgical procedure. All the S. aureus strains identified on PCR assay were susceptible to methicillin and mupirocin. The rate of S. aureus infection was 3.4% (17 of 504 patients) in the mupirocin-chlorhexidine group, as compared with 7.7% (32 of 413 patients) in the placebo group (relative risk of infection, 0.42; 95% confidence interval [CI], 0.23 to 0.75). The effect of mupirocin-chlorhexidine treatment was most pronounced for deep surgical-site infections (relative risk, 0.21; 95% CI, 0.07 to 0.62). There was no significant difference in all-cause in-hospital mortality between the two groups. The time to the onset of nosocomial infection was shorter in the placebo group than in the mupirocin-chlorhexidine group (P=0.03). CONCLUSIONS: The number of surgical-site S. aureus infections acquired in the hospital can be reduced by rapid screening and decolonizing of nasal carriers of S. aureus on admission. (Current Controlled Trials number, ISRCTN56186788.

Cohort included a variety of surgical procedures, as well as patients hospitalized for medical issues.

→ Supports treatment of nasal carriers of Staphylococcus aureus to reduce incidence of surgical site infections.

II / C / 1 / c
Reducing nasal colonization; Reducing skin colonization; Chlorhexidine

PMID: 21507604

Abstract: We quantified surgical site infections (SSIs) after preoperative screening/selective decolonization before elective total joint arthroplasty (TJA) with 2-year follow-up and 2 controls. Concurrent controls (n = 2284) were patients of surgeons not participating in screening/decolonization. Preintervention controls (n = 741) were patients of participating surgeons who underwent TJA the previous year. Staphylococcus aureus nasal carriers (321/1285 [25%]) used intranasal mupirocin and chlorhexidine baths as outpatients. Staphylococcal SSIs occurred in no intervention patients (0/321) and 19 concurrent controls. If all SSIs occurred in carriers and 25% of controls were carriers, staphylococcal SSI rate would have been 3.3% in controls (19/571; P = .001). Overall SSI rate decreased from 2.7% (20/741) in reintervention controls to 1.2% (17/1440) in intervention patients (P = .009). Preoperative screening/selective decolonization was associated with fewer SSIs after elective TJA.

Cohort includes patients undergoing total joint replacement.

→ Supports the use of mupirocin nasal swabs and chlorhexidine bath to reduce surgical site infections after total joint surgery.
Delirium & Adverse Outcomes

Delirium


The presence of delirium in LD-treated patients was associated with an increased mortality rate (6.1 vs. 0.8 per 1000; P < 0.001). Logistic regression demonstrated that independent predictors of delirium included older age (≥65 yr), alcohol/drug abuse, depression, psychotic disorders, neurological disorders, deficiency anemia, fluid/electrolyte disorders, and weight loss. The incidence of delirium in LD-treated patients was statistically greater than in LF-treated patients (OR, 2.41 [95% CI, 1.77-3.29]; I(2), 0%; 6 studies; average follow-up, 2.3-15 years; 321/286,280 patients [11.1%] with delirium and 249,886/2,085,119 controls [12.1%]; odds ratio [OR], 2.41 [95% CI, 1.77-3.29]; I(2), 0%)

STUDY DESIGN: Retrospective database analysis.

OBJECTIVE: A population-based database analysis to characterize the incidence, hospital costs, mortality, and risk factors associated with postoperative delirium after lumbar decompression (LD) and lumbar fusion (LF) surgical procedures.

SUMMARY OF BACKGROUND DATA: Postoperative delirium is a common complication after surgery in the elderly that leads to increased hospitalization, cost, and other adverse outcomes. The incidence of delirium after lumbar spine surgery has not been discussed in this literature.

METHODS: Data from the Nationwide Inpatient Sample were obtained from 2002-2009. Patients undergoing LD or LF for degenerative pathologies were identified. Patient demographics, comorbidities, length of stay, discharge disposition, costs, and mortality were assessed. A P value of less than 0.001 was used to denote significance. Independent T tests for discrete variables and χ2 tests for categorical data. Logistic regression was performed to identify independent predictors of delirium. A P value of less than 0.001 was used to denote significance. The overall incidence of delirium was 8.4 events per 1000 cases. Patients undergoing LD had a statistically greater incidence of delirium than patients undergoing LF (11.8 vs. 5.5 per 1000; P < 0.001). Patients experiencing delirium were significantly older and more likely to be female than unaffected patients (P < 0.001). Patients with delirium in both cohorts demonstrated significantly greater comorbidities, length of stay, greater costs, and more frequent discharge to skilled nursing facilities (P < 0.001). The presence of delirium in LD-treated patients was associated with an increased mortality rate (OR, 2.41 [95% CI, 1.77-3.29]; I(2), 0%; 6 studies; average follow-up, 2.3-15 years; 321/286,280 patients [11.1%] with delirium and 249,886/2,085,119 controls [12.1%]; odds ratio [OR], 2.41 [95% CI, 1.77-3.29]; I(2), 0%)

CONCLUSION: The results of our study demonstrated an overall incidence of 8.4 events per 1000 lumbar spine surgical procedures. Overall analysis demonstrated an increased incidence of delirium in older females with more comorbid conditions. Future research should be focused on being associated with increased length of stay, costs, and mortality in all patients undergoing lumbar spine surgery. We recommend that physicians put greater effort into recognizing the risk factors of delirium and diagnosing it in a timely manner to mitigate its effects.

Increased mortality (6.1 vs. 0.8 per 1000; P < 0.001). Logistic regression demonstrated that independent predictors of delirium included older age (≥65 yr), alcohol/drug abuse, depression, psychotic disorders, neurological disorders, deficiency anemia, fluid/electrolyte disorders, and weight loss.

Delirium in elderly patients treated in hospital or acute care setting for medical or surgical conditions. Supports the conclusion that delerium is associated with poor outcomes. 8. The incidence of delirium in LD-treated patients was statistically greater than in LF-treated patients (OR, 2.41 [95% CI, 1.77-3.29]; I(2), 0%; 6 studies; average follow-up, 2.3-15 years; 321/286,280 patients [11.1%] with delirium and 249,886/2,085,119 controls [12.1%]; odds ratio [OR], 2.41 [95% CI, 1.77-3.29]; I(2), 0%).

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From the Nationwide Inpatient Sample including 2,085,119 lumbar decompressions and lumbar fusions. Logistic regression analysis identified odds ratio for delirium at 2.3 for patients with alcohol abuse versus no alcohol abuse. Criteria for “alcohol abuse” not specified and may have been taken from coding data from NIS.

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Summary of Evidence

Delirium is a common and serious complication in elderly patients. Evidence suggests that delirium is associated with long-term poor outcome but delirium often occurs in individuals with more severe underlying disease. OBJECTIVE: To assess the association between delirium in elderly patients and long-term poor outcome, defined as mortality, institutionalization, or dementia, while controlling for important confounders.

METHODS: A systematic review of studies published between January 1981 and April 2010 was conducted using the databases of MEDLINE, EMBASE, PsychInfo, and Cochrane. STROBE (Standards for Reporting of Observational Studies in Epidemiology) guidelines were used for cohort studies. The primary analysis included only high-quality studies with statistical control for age, sex, comorbid illness or illness severity, and baseline dementia. Pooled-effect estimates were calculated with random-effects models. The primary analysis with adjusted hazard ratios (HRs) showed that delirium is associated with an increased risk of death compared with controls after an average follow-up of 2.7 months (7 studies; 275/734 patients [37.1%] with delirium, 662/2241 controls [29.6%]; HR, 1.97 [95% confidence interval (CI), 1.33-2.92]; I(2), 44%). Moreover, patients who had experienced delirium were at an increased risk of institutionalization (7 studies; average follow-up, 16 months; 136/257 patients [52.6%] with delirium and 318/2025 controls [15.7%]; odds ratio [OR], 4.81 [95% CI, 1.77-13.0]; I(2), 0%) and dementia (2 studies; average follow-up, 4.1 years; 273/782 patients [34.7%] with delirium and 203/200 controls [10.1%]; OR, 2.32 [95% CI, 1.28-4.21]; I(2), 42%). The sensitivity, trim-and-fill, and secondary analyses with unadjusted high-quality risk estimates stratified according to the study characteristics confirmed the robustness of these results. CONCLUSION: This meta-analysis provides evidence that delirium in elderly patients is associated with poor outcomes independent of important confounders, such as age, sex, comorbid illness or illness severity, and baseline dementia.

Context: Delirium is a common and serious complication in elderly patients. Evidence suggests that delirium is associated with long-term poor outcome but delirium often occurs in individuals with more severe underlying disease.
Cycle 3: Optimal surgical process

OBJECTIVES: To determine the efficacy of surgery in the management of patients with symptomatic lumbar spinal stenosis. Moreover, the superiority of these new surgical procedures over traditional decompression surgery is still unclear. OBJECTIVES: To determine the efficacy of surgery in the management of patients with symptomatic lumbar spinal stenosis and the comparative effectiveness between routinely performed surgical techniques and the condition on patient-related outcomes. The secondary outcomes included measurements related to surgery, such as perioperative blood loss, operation time, length of hospital stay, reoperation rates, and costs. We grouped trials according to the types of surgical interventions being compared and categorised follow-up times as short-term when less than 12 months and long-term when 12 months or more. The Cochrane Back and Neck Review Group criteria. Reviewers also extracted demographics, surgery details, and clinical groups using an online panel and clinic recruitment. A scale-setting subsample was created reflecting demographics proportional to the 2000 U.S. census. RESULTS: Using item-response theory (graded response model), 12 item banks were calibrated in a sample of 21,133, measuring components of self-reported physical, mental, and social health, along with a 10-item Global Health Scale. Short forms from each bank were developed and compared with the overall bank and with other well-validated and widely accepted (‘legacy’) measures. All item banks demonstrated good reliability across most of the score distributions. Construct validity was supported by moderate to strong correlations with legacy measures. CONCLUSION: PROMIS item banks and their short forms provide evidence that they are reliable and precise measures of generic symptoms and functional results comparable to legacy instruments. Further testing will continue to validate and test PROMIS item banks and forms in diverse clinical populations.

Test cohort reflected demographics proportional to US population, not individual subsets of population. Validates the PROMIS tool to measure patient-related outcomes.

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The effects of the interventions. Summary of Background Data: Complication rates in adult spinal deformity surgery are unacceptable. System approaches are necessary to increase patient safety. This group expanded on the double-blind surgery approach, a multidisciplinary perioperative screening conference, and the intraoperative protocol for management of coagulopathy. The outcomes were demonstrated by complication rates before and after the initiation of this protocol. Methods: Forty consecutive patients in Group A were managed with the 3-pronged approach. A total of 124-consecutive patients in Group B a double-blinding surgery approach, were presented and cleared by a live multidisciplinary perioperative conference, and were managed according to the intraoperative protocol. Results: Group A had an average age of 66 years (range, 28-86 years). Group B had an average age of 66 years (range, 28-86 years). Most patients in both groups had fusions from 9 to 15 levels. Complication rates in Group A were significantly lower (10% vs. 21%) (p < 0.01). Group B showed significantly lower rates of wound infection requiring debridement (1.6% vs. 7.5%), lower rates of deep vein thrombosis/pulmonary embolism (2% vs. 10%), and lower rates of postoperative neurological complications (0.5% vs. 2.5%) (not significant). Group B had significantly lower rates of urinary tract infection requiring antibiotics (5.7% vs. 12.5%) (p < 0.001). Conclusions: These data suggests that a group approach consisting of a double-blind surgeon approach in the operating room, a live presurgical screening conference, and an intraoperative protocol for managing coagulopathy will significantly reduce complication rates and enhance patient safety in patients undergoing complex spinal reconstructions for adult spinal deformity. _ 2014 Scoliosis Research Society_.

BACKGROUND CONTEXT: The importance of surgeon volume as a quality measure has been determined for a number of surgical specialties. Meaningful procedural volume benchmarks have not been established, however, particularly with respect to lumbar spine surgery.

PURPOSE: We aimed to establish surgeon volume benchmarks for the performance of four common lumbar spine surgical procedures (discectomy, decompression, lumbar interbody fusion, and lumbar posterior fusions).

STUDY DESIGN: A retrospective review of data from the Florida Statewide Inpatient Dataset (2011-2014) was carried out.

PATIENT SAMPLE: Patients who underwent one of the four lumbar spine surgical procedures under study comprised the study sample.

OUTCOME MEASURE: The development of a complication or hospital readmission within 90 days of the surgical procedure was the surgical outcome.

METHODS: For each specific procedure, individual surgeon volume was separately plotted against the number of complications and readmissions in a spline analysis that adjusted for co-variates. Spline cut-points were used to create a categorical variable of procedure volume for each individual procedure. Log binomial regression analysis was then separately performed using the categorical volume-outcome metric for each individual procedure and for the outcomes of 90-day complications and 90-day readmissions.

RESULTS: In all, 187,185 spine surgical procedures met inclusion criteria, performed by 3,514 different surgeons at 119 hospitals. Spline analysis determined that the procedure volume cut point was 25 for decompression, 45 for discectomy, 45 for interbody fusion, and 35 for postlateral fusions. For surgeons who failed to meet the volume metric, there was a 50% increase in the risk of complications following decompressions, a 50% increase in the risk of complications following discectomy, a 5% increase in the risk of complications following interbody fusions, and a 47% increase in the risk of complications following postlateral fusions. Surgical outcomes were similar for readmission.

CONCLUSIONS: The results of this work allow us to identify meaningful volume-based benchmarks for the performance of common lumbar spine surgical procedures including discectomies, decompressions, discectomy, and fusion/posterior procedures. Based on our determinations, readily achievable goals for individual surgeons would be to accumulate 25 surgeries for decompression, 45 for discectomy, 45 for interbody fusion, and 35 for postlateral fusion. Beyond these thresholds, complication and readmission rates increased significantly. A professional society statement on managing presence of industry representatives in the operating room.

Surgical volume

October 21, 2014

Page 21 of 40 September 2014 - Bree Collaborative Lumbar Fusion Evidence Table

Cohort comprised of general and cardiovascular surgery in VA system.

 hôpital trades, 67% of patients who underwent surgery between 4 pm and 6 pm were associated with an elevated risk of morbidity (OR = 1.25, P = <0.005) over those starting between 7 am and 4 pm. Operations starting after 6 pm were associated with an elevated risk of complications (OR = 1.46, P = <0.005). CONCLUSIONS: When considering a nonemergency procedure, surgeons must bear in mind that cases that start after routine "business" hours within the VA system may face an elevated risk of complications that warrants further evaluation.

Industry reps in OR

American College of Surgeons, 5th-35th attainment of healthcare industry representatives in the operating room. Revised October 2016.

The ACS recognizes the need for a structural system within the perioperative setting to allow for education, training, and introduction of procedures, techniques, technology, and equipment to the surgical health care team. Health care industry representatives (HCR) by virtue of their training, knowledge, and expertise, often can provide technical assistance to the surgical team. Such assistance may expedite the procedure and may facilitate the safe and effective application of surgical products and technologies. The purpose of this statement is to supply guidelines to health care facilities and members of the perioperative care team to ensure optimal surgical outcomes, to ensure patient safety, and to protect patients' rights to privacy and confidentiality when an HCR is present during a surgical procedure.
Acetaminophen, nonsteroidal antiinflammatory drugs, or selective cyclooxygenase-2 inhibitors all reduce morphine need after surgery.

Intraoperative ketamine reduces perioperative opiate consumption in opiate-dependent patients receiving average of 1.6-2.0 level lumbar fusions.

The authors analyzed data from 12 randomized placebo-controlled trials (3,613 subjects) testing acetaminophen, nonsteroidal antiinflammatory drugs, or selective cyclooxygenase-2 inhibitors given in conjunction with morphine after surgery. The median of the average 24-h morphine consumption in controls was 49 mg (range, 18.0-22.0 mg) (number needed to treat, 15) and of sedation from 15.4% to 12.7% (number needed to treat, 15).

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Monotherapy; Reducing colonization; Reducing nasal colonization

Cannella BA, Crossett LS, Yates AJ, McGough RL, Hamilton CW.


Introduction: The CMS Surgical Care Improvement Project (SCIP) measures are a subset of National Quality Hospital Measures created through the joint efforts of the Centers for Medicare & Medicaid and the Joint Commission (Specifications Manual for National Hospital Quality Measures Version 2.5 effective for discharges 10-01-2008 through 03-31-2009). The SCIP measures have been endorsed by the National Quality Forum, and are used by Hospital Compare, the Premier demonstration, and RHQDAPU. Corresponding measures are used by the CMS as standards for measures to prevent infection and venous thromboembolism for surgical patients.

→ CMS standard for measures to prevent infection and venous thromboembolism for surgical patients.

Cohort is orthopedic patients.

→ Supports the use of mupirocin nasal swabs and chlorhexidine bath to reduce surgical site infections after total joint surgery.

Cochrane Database of Systematic Reviews 2013, Issue 10. Art. No.: CD007402.

Cohort is arthroplasty patients.

→ Provides modest support for use of TXA to reduce blood loss and transfusion need in spinal surgery patients.

Meta-analysis of high-quality studies. Heterogeneity of some outcomes. Insufficient safety data. Are blood loss and transfusion needs intermediate or patient-oriented outcomes?
Tranexamic acid to reduce bleeding


Tranexamic Acid reduces perioperative blood loss in adult patients having spinal fusion surgery. Anesth Analg. 2008 Nov;107(5):1479-86. PMID: 18931202

BACKGROUND: Spinal reconstructive surgery in adults can be associated with significant blood loss, often requiring allogeneic blood transfusion. The objective of this randomized, prospective, double-blinded, multicenter study was to evaluate the efficacy of tranexamic acid (TXA) in reducing perioperative blood loss and transfusion in adult patients having elective posterior thoracic/lumbar instrumented spinal fusion surgery. METHODS: One hundred fifty-one adult patients were randomized to receive a bolus of 10 mg/kg IV of TXA after induction followed by a maintenance infusion of 1 mg/kg/hr of TXA, or an equivalent volume of placebo (normal saline). The primary outcome was the total perioperative estimated and calculated blood loss measured intraoperatively and 24 h postoperatively. Secondary outcomes were incidence of allogeneic blood exposure, and duration of hospital stay. RESULTS: Four patients were withdrawn for identifiable surgical bleeding, therefore 147 patients were included in the analysis. The total estimated and calculated perioperative blood loss was approximately 29% and 30% lower in patients given TXA versus placebo (1592 +/- 1315 mL vs 2138 +/- 1807 mL, P = 0.026; 3079 +/- 2558 vs 4363 +/- 3030, P = 0.017), respectively. There was no difference in the amounts of blood products transfused, and length of stay between the two groups. TXA, surgical duration, and number of vertebral fusions were independent factors related to perioperative blood loss. Prognostic factors for the need for allogeneic red blood cell transfusion were ASA classification, surgical duration and number of levels fused. CONCLUSIONS: TXA significantly reduced the estimated and calculated total amount of perioperative blood loss in adult patients having elective thoracic/lumbar instrumented spinal fusion surgery. High-quality RCT showing that tranexamic acid reduces blood loss in patients undergoing spinal fusion surgery. 2/B grade based on the outcome was intermediate (blood loss), insufficient safety data (see citation #60).
The article discusses the prevention of venous thromboembolism (VTE) in part of the Antithrombotic and Thrombolytic Therapy: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Grade 1 recommendations are strong and indicate that the benefits do or do not outweigh risks, benefits, and costs. Grade 2 suggestions imply that individual patient values may lead to different choices than a full discussion of the grading, see the “Grades of Recommendation” chapter by Guyatt et al. Among the key recommendations in this chapter are the following: we recommend that every hospital develop a formal strategy that addresses the prevention of VTE (Grade 1A). We recommend against the use of aspirin alone as thromboprophylaxis for any patient group (Grade 1A), and we recommend that mechanical methods of thromboprophylaxis be used primarily for patients at high bleeding risk (Grade 1A) or possibly as an adjunct to anticoagulant thromboprophylaxis (Grade 2A). For patients undergoing major general surgery, we recommend thromboprophylaxis with a low-molecular-weight heparin (LMWH), low-dose unfractionated heparin (UFH), or fondaparinux (each Grade 1A). We recommend routine thromboprophylaxis for all patients undergoing major general surgery or major, open urological procedures (Grade 1A for both groups), with LMWH, UFH, fondaparinux, or intermittent pneumatic compression (IPC). For patients undergoing elective hip or knee arthroplasty, we recommend one of the following three anticoagulant agents: LMWH, fondaparinux, or a vitamin K antagonist (VKA) international normalized ratio (INR) target, 2.5; range, 2.0 to 3.5 (each Grade 1A) for patients undergoing hip fracture surgery (HFS). We recommend the routine use of fondaparinux (Grade 1A), LMWH (Grade 1A), or UFH (Grade 1B) for patients undergoing hip or knee arthroplasty or HFS receive thromboprophylaxis for a minimum of 10 days (Grade 1A). For hip arthroplasty and HFS, we recommend continuing thromboprophylaxis > 10 days and up to 30 days (Grade 3A). We recommend that all major trauma and all spinal cord injury (SCI) patients receive thromboprophylaxis (Grade 1A). In patients admitted to hospital with an acute medical illness, we recommend thromboprophylaxis with LMWH, UFH, or fondaparinux (each Grade 1A). We recommend that, on admission to the ICU, all patients be assessed for their risk of VTE, and that most receive thromboprophylaxis (Grade 1A).

Observational studies relating perioperative blood sugar levels to adverse outcomes. Cohort included a variety of surgical procedures obtained from operating room electronic medical records. Patients stratified according to severity of surgery. Study does not appear to control for all variable that may have influenced outcomes.

→ Supports the conclusion that peri-operative hyperglycemia is associated with post-operative complications.
Early mobilization

BACKGROUND: Recovery after spinal fusion continues to be refined through better multidisciplinary care, various recovery protocols exist, all which incorporate and emphasize early and immediate postoperative mobilization. Mobilizing patients on the day of surgery is thought to improve functional recovery of range of motion and reduce hospital length of stay (LOS). METHODS: All patients undergoing elective primary repair or revision spinal fusion between August 2010 and June 2011 within a four-hospital health system were retrospectively reviewed. Patients evaluated by physical therapy (PT) the day of surgery were included in the study analysis. Ambulation was attempted the day of surgery with PT, with or without the use of assistive devices. If a distance of at least 30 feet was not reached, a questionnaire indicating the reasons was completed. Distance ambulated on the day of surgery, obstacles impeding ambulating 30 feet, and LOS were recorded. Patients reaching the in-patient unit after 18:00 hours were excluded. RESULTS: Seventy percent of patients (320/471) successfully ambulated at least 30 feet on the day of surgery. Forty seven patients were not evaluated secondary to personal related factors. A total of 35 patients ambulated under 30 feet, citing most commonly: orthostasis/hypotension 20.6% (9/35), drowsiness 25.9% (20/35), nausea 23.5% (20/85), pain 37.1% (25/85), dizziness 15% (5/85), fatigue 14.3% (2/85), and joint (1%), limiting reasons. The average LOS of patients ambulating at least 30 feet the day of surgery was 1.85 days versus 2.79 days in those ambulating less (p<0.05). CONCLUSIONS: The benefits of early postoperative mobilisation are well recognised and this study highlights major obstacles limiting early ambulation after spinal fusion. Focusing continued multidisciplinary efforts towards such facets as postoperative hypotension, nausea, drowsiness, and pain after elective spinal fusion may further improve our development of rapid recovery programs. Furthermore, ambulating a distance of at least 30 feet the day the surgery correlates with a statistically significant shorter LOS.