Norwegian Registry for Spine Surgery (NORspine)

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Loss to follow-up may bias outcome assessments in medical registries. A cohort study aimed to analyze and compare patients who failed to respond with those that responded to the Norwegian Registry for Spine Surgery (NORspine).

They analyzed a cohort of 474 consecutive patients operated for lumbar spinal stenosis at four public hospitals in Norway during a two-year period. These patients reported sociodemographic data, preoperative symptoms, and Oswestry Disability Index (ODI), numerical rating scales (NRS) for back and leg pain to NORspine at baseline and 12 months postoperatively. They contacted all patients who did not respond to NORspine after 12 months. Those who responded were termed responsive non-respondents and compared to 12 months respondents.

One hundred forty (30%) did not respond to NORspine 12 months after surgery and 123 were available for additional follow-up. Sixty-four of the 123 non-respondents (52%) responded to a cross-sectional survey done at a median of 50 (36-64) months after surgery. At baseline, non-respondents were younger 63 (SD 11.7) vs. 68 (SD 9.9) years (mean difference (95% Cl) 4.7 years (2.6 to 6.7); p = < 0.001) and more frequently smokers 41 (30%) vs. 70 (21%) RR (95%Cl) = 1.40 (1.01 to 1.95); p = 0.044. There were no other relevant differences in other sociodemographic variables or preoperative symptoms. We found no differences in the effect of surgery on non-respondents vs. respondents (ODI

(SD) = 28.2 (19.9) vs. 25.2 (18.9), MD (95%CI) = 3.0 (-2.1 to 8.1); p = 0.250).

Kaur et al. found that 30% of patients did not respond to NORspine at 12 months after spine surgery. Non-respondents were somewhat younger and smoked more frequently than respondents; however, there were no differences in patient-reported outcome measures. The findings suggest that attrition bias in NORspine was random and due to non-modifiable factors. ¹⁾.

Data were obtained from the Norwegian Registry for Spine Surgery. The primary outcome was change in the neck disability index (NDI) 1 yr after surgery. Secondary endpoints were the European myelopathy score (EMS), quality of life (EuroQoL 5D [EQ-5D]), numeric rating scales (NRS) for headache, neck pain, and arm pain, complications, and perceived benefit of surgery assessed by the Global Perceived Effect (GPE) scale.

They included 905 patients operated between January 2012 and June 2018. There were significant improvements in all patient-reported outcome measures (PROMs) including NDI (mean -10.0, 95% CI -11.5 to -8.4, P < .001), EMS (mean 1.0, 95% CI 0.8-1.1, P < .001), EQ-5D index score (mean 0.16, 95% CI 0.13-0.19, P < .001), EQ-5D visual analogue scale (mean 13.8, 95% CI 11.7-15.9, P < .001), headache NRS (mean -1.1, 95% CI -1.4 to -0.8, P < .001), neck pain NRS (mean -1.8, 95% CI -2.0 to -1.5, P < .001), and arm pain NRS (mean -1.7, 95% CI -1.9 to -1.4, P < .001). According to GPE scale assessments, 229/513 patients (44.6%) experienced "complete recovery" or felt "much better" at 1 yr. There were significant improvements in all PROMs for both mild and moderate-to-severe DCM. A total of 251 patients (27.7%) experienced adverse effects within 3 mo.

Surgery for DCM is associated with significant and clinically meaningful improvement across a wide range of PROMs²⁾.

multicenter cohort study included 11,081 patients operated with lumbar microdiscectomy, registered at the Norwegian Registry for Spine Surgery. Follow-up was 1 year. Uni- and multivariate logistic regression analyses were used to assess potential prognostic factors for previously defined cut-offs for failure and worsening on the Oswestry Disability Index scores 12 months after surgery. Since the cut-offs for failure and worsening are different for patients with low, moderate, and high baseline ODI scores, the multivariate analyses were run separately for these subgroups. Data were split into a training (70%) and a validation set (30%). The model was developed in the training set and tested in the validation set. A prediction (%) of an outcome was calculated for each patient in a risk matrix.

Results: The prognostic model produced six risk matrices based on three baseline ODI ranges (low, medium, and high) and two outcomes (failure and worsening), each containing 7 to 11 prognostic factors. Model discrimination and calibration were acceptable. The estimated preoperative probabilities ranged from 3 to 94% for failure and from 1 to 72% for worsening in our validation cohort.

Conclusion: We developed a prognostic model for failure and worsening 12 months after surgery for lumbar disc herniation. The model showed acceptable calibration and discrimination, and could be useful in assisting physicians and patients in clinical decision-making process prior to surgery ³⁾.

A study is based on data from the Norwegian Registry for Spine Surgery (NORspine). Patients who had decompressive surgery in the period from 7/1-2007 to 11/3-2013 at 31 hospitals were included. The patients was divided into four groups based on preoperative Numeric Rating Scale (NRS)-score for lower extremity pain. Patients in group 1 had insignificant pain, group 2 had mild or moderate pain, group 3 severe pain and group 4 extremely severe pain. The primary outcome was change in the Oswestry Disability Index (ODI). Successfully treated patients were defined as patients reporting at least 30% reduction of baseline ODI, and the number of successfully treated patients in each group were recorded.

Results: In total, 3181 patients were eligible; 154 patients in group 1; 753 in group 2; 1766 in group 3; and 528 in group 4. Group 1 had significantly less improvement from baseline in all the clinical scores 12 months after surgery compared to the other groups. However, with a mean reduction of 8 ODI points and 56% of patients showing a reduction of at least 30% in their ODI score, the proportion of patients defined as successfully treated in group 1, was not significantly different from that of other groups.

Conclusion: This national register study shows that patients with insignificant lower extremity pain had less improvement in primary and secondary outcome parameters from baseline to follow-up compared to patients with more severe lower extremity pain ⁴⁾.

A total of 6840 patients with lumbar disc herniation were operated and followed for 12 months, according to the standard protocol of the Norwegian Registry for Spine Surgery (NORspine). Patients reporting to be unchanged or worse on the Global Perceived Effectiveness (GPE) scale at 12-month follow-up were classified as "failure", and those considering themselves "worse" or "worse than ever" after surgery were classified as "worsening". These two dichotomous outcomes were used as anchors in analyses of receiver operating characteristics (ROC) to define cutoffs for failure and worsening on commonly used PROMs, namely, the Oswestry Disability Index (ODI), the EuroQuol 5D (EQ-5D), and Numerical Rating Scales (NRS) for back pain and leg pain.

Results: "Failure" after 12 months for each PROM, as an insufficient improvement from baseline, was (sensitivity and specificity): ODI change <13 (0.82, 0.82), ODI% change <33% (0.86, 0.86), ODI final raw score >25 (0.89, 0.81), NRS back-pain change <1.5 (0.74, 0.86), NRS back-pain % change <24 (0.85, 0.81), NRS back-pain final raw score >5.5 (0.81, 0.87), NRS leg-pain change <1.5 (0.81, 0.76), NRS leg-pain % change <39 (0.86, 0.81), NRS leg-pain final raw score >4.5 (0.91, 0.85), EQ-5D change <0.10 (0.76, 0.83), and EQ-5D final raw score >0.63 (0.81, 0.85). Both a final raw score >48 for the ODI and an NRS >7.5 were indicators for "worsening" after 12 months, with acceptable accuracy.

Conclusion: The criteria with the highest accuracy for defining failure and worsening after surgery for lumbar disc herniation were an ODI percentage change score <33% for failure and a 12-month ODI raw score >48. These cutoffs can facilitate shared decision-making among doctors and patients, and improve quality assessment and comparison of clinical outcomes across surgical units. In addition to clinically relevant improvements, we propose that rates of failure and worsening should be included in reporting from clinical trials ⁵⁾.

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