Baseline Patient Characteristics Commonly Captured Before Surgery Do Not Accurately Predict Long-Term Outcomes of Lumbar Microdiscectomy Followed by Physiotherapy

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Study Design. Prospective cohort study.
Objective. To develop and internally validate prognostic models based on commonly collected preoperative data for good and poor outcomes of lumbar microdiscectomy followed by physiotherapy.

Summary of Background Data. Lumbar microdiscectomy followed by physiotherapy is a common intervention for lumbar radiculopathy. Postoperatively, a considerable percentage of people continues to experience pain and disability. Prognostic models for recovery are scarce.

Methods. We included 298 patients with lumbar radiculopathy who underwent microdiscectomy followed by physiotherapy. Primary outcomes were recovery and secondary outcomes were pain and disability at 12 months follow-up. Potential prognostic factors were selected from sociodemographic and biomedical data commonly captured preoperatively. The association between baseline characteristics and outcomes was evaluated using multivariable logistic regression analyses.

Results. At 12 months follow-up, 75.8% of the participants met the criterion for recovery. Variables in the model for good recovery included: younger age, leg pain greater than back pain, high level of disability, and a disc herniation at another level than L3–L4. The model for poor recovery included: lower educational level, prior back surgery, and disc herniation at L3–L4. Following internal validation, the explained variance (Nagelkerke $R^2$) and area under the curve for both models were poor ($<0.02$ and $<0.60$, respectively). The discriminative ability of the models for disability and pain were also poor.

Conclusion. The outcome of microdiscectomy followed by postoperative physiotherapy cannot be predicted accurately by commonly captured preoperative sociodemographic and biomedical factors. The potential value of other biomedical, personal, and external factors should be further investigated.

Key words: biopsychosocial, low back pain, musculoskeletal health, neurosurgery, orthopedics, physiotherapy, prediction, prognosis, rehabilitation, surgery.

Level of Evidence: 3

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Surgery for lumbar radiculopathy is considered when appropriate conservative treatment is unsuccessful. In the United States, about 250,000 operations for lumbar radiculopathy are performed each year. The reported success rate of lumbar disc surgery varies widely. Reoperation rates are approximately 9% within 2 years. Prognostic research is needed to assist surgeons and clinicians to adequately predict the outcome after discectomy.

According to the literature, only four prognostic models have been derived to predict recovery after lumbar microdiscectomy. Biomedical and psychosocial factors were considered in three of these models with low to moderate performance. However, in current clinical practice, psychosocial factors are not routinely assessed.

To the best of our knowledge, there is only one prognostic model based on routinely collected baseline variables which predict the outcome of lumbar discectomy and therefore is representative for clinical care. However, this model was
derived retrospectively, and there is a need to conduct prospective prognostic studies that are based on usual care data. Besides, none of the previously derived models have been internally and externally validated.

Therefore, we conducted a prospective study to build and internally validate prognostic models for good and poor outcomes of lumbar microdiscectomy followed by physiotherapy by using data commonly captured before surgery.

MATERIALS AND METHODS

Design
We conducted a prospective cohort study with 12 months follow-up. All patients provided written informed consent prior to participating in the study. The Medical Ethics Review Board of the Elisabeth Hospital in Tilburg, The Netherlands, approved the study (METC-T2012–11). The methods and results are reported in accordance with recommendations made in the Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD) guideline.13

Participants
Patients with clinical signs and symptoms of lumbosacral nerve root compression and magnetic resonance imaging findings (MRI) of disc pathology at a corresponding level who were already scheduled for lumbar microdiscectomy were eligible to participate in the study. Participants had to be at least 18 years of age, and proficient in Dutch to complete the questionnaires.

Exclusion criteria were pregnancy and signs and symptoms of serious pathologies, such as cauda equine syndrome, neoplasm or fracture. Patients were recruited through the ViaSana Clinic in Mill, The Netherlands.

Lumbar microdiscectomy relieved pressure on the lumbar nerve root by removing a part of the disc and the ligament flavum. This was performed by a microscope.

All patients received a postoperative physiotherapy session at the clinic the day after the surgery consisting of information about recovery, guidelines for home, and exercises. At discharge, patients received a physiotherapy treatment plan to conduct with a primary care physiotherapist with the goals to resume daily activities, work, and sports. The means to achieve this were by improving knowledge and understanding, mobility, muscle strength and endurance, and performance of functional activities, such as walking and cycling. No maximum number of sessions or the duration of treatment was provided.

Criteria for Good and Poor Recovery
The primary outcomes were good and poor recovery. Recovery was measured on a 7-point General Perceived Effect (GPE) scale.14,15 To determine success in the analysis, the scale was dichotomized: “completely recovered” or “much improved” were considered to reflect good recovery; whereas “slightly improved,” “not changed,” “slightly worsened,” “much worsened,” and “worse than ever” were considered poor recovery.

The secondary outcomes were pain and disability. We defined “no or minimal pain” as a pain intensity less than or equal to 20 on a 0 to 100 Visual Analogue Scale “VAS” and “pain” as more than 20 points.14,15 “No or minimal disability” was defined as a score of less than or equal to 5 points on the Roland Morris Disability Questionnaire (RMDQ) and “disability” as more than 5 points on the RMDQ.14–16

Candidate Prognostic Factors
Prognostic factors were selected from baseline data commonly captured before lumbar disc surgery. Factors were obtained in the following five domains: sociodemographic, previous medical history, signs and symptoms, medical imaging, and work. Factors were selected based on previous systematic reviews which revealed at least moderate evidence for a univariable association with the outcomes of lumbar disc surgery.17–19 Additionally, prognostic factors judged relevant by a clinical expert panel consisting of a neurosurgeon, two orthopedic surgeons, and a physiotherapist were also considered. Appendix A, http://link. lww.com/BRS/B517 summarizes all potential prognostic factors for each outcome. The number of selected factors per outcome varied depending on the percentage of (non)recovery.

Data Collection
All baseline variables were collected in the week before surgery during the routine preoperative patient interview and clinical examination by the orthopedic surgeon or neurosurgeon. The outcome measures to determine success were collected at 12 months postoperatively using Online-PROMS, an internet-based platform designed to collect questionnaire data (Interactive Studios, Rosmalen, The Netherlands). Patients who preferred paper-based forms received the questionnaires via mail. Reminders were sent to non-responders 7 and 14 days after the scheduled follow-up time-point. Patients who did not or only partly completed the questionnaires were approached once by telephone and encouraged to complete the questionnaires.

Sample Size
Previous research revealed a 60% to 70% success rate for recovery and disability at 12 months following discectomy surgery.7 Considering the rule of thumb of 10 participants per potential predictor variable in the limiting sample, and our intention to include 10 predictor variables in the prognostic models, 286 patients are required (100 participants in the non-success [or 35%] group, plus 186 participants in the success [or 65%] group).13

Statistical Analysis
Descriptive analyses were performed to describe patient characteristics and outcomes. The relationship between predictor variables and outcomes was evaluated using
multivariable logistic regression analyses with a backward Wald selection. All assumptions (linearity between independent continuous variables, log odds, and multicollinearity) were checked before model building. Missing value analyses were performed by assuming the missing at random (MAR) assumption. This was evaluated by comparing the main baseline characteristics by using \( t \) tests to observe if there were any differences between participants with missing values and participants with complete data sets. Multiple imputation was applied by the multivariate imputation by chained equations (MICE) method with predictive mean matching (PMM). Sixteen imputed datasets were generated corresponding to the highest missing value percentage. Multiple imputation was performed for missing data in the predictors and outcome variables.\(^{20}\) Pooled results from the imputed analyses were compared with complete case analyses. Candidate predictors were entered in the multivariable regression analysis and a backward Wald selection procedure was used to determine which variables were kept in the model (final model, \( P < 0.157 \)).\(^{21,22}\) The quality of the multivariable model was determined with Hosmer–Lemeshow goodness-of-fit statistic and the explained variance with Nagelkerke \( R^2 \).\(^{23}\) Discriminative ability of the models was assessed using the area under the receiver-operating characteristic curve. An area under the curve (AUC) of 0.5 indicates poor discrimination above chance, 0.7 indicates fair discrimination, 0.8 indicates acceptable discrimination, whereas an AUC of 1.0 indicates perfect discrimination.\(^{23}\) The median was calculated for Nagelkerke \( R^2 \) and AUC for the imputed datasets.\(^{24}\)

To correct for overfitting, the internal validity of the models was assessed through bootstrapping techniques with 500 repetitions. All analyses were performed by using SPSS version 25.0 (Inc., Chicago, IL), except the bootstrapping which was performed in R 3.4.4.

**RESULTS**

**Study Population**

Of the 333 consecutive patients scheduled for lumbar microdiscectomy, 298 patients participated in the study. Figure 1 shows the participant flow diagram and Table 1 summarizes the baseline characteristics.

**Lost to Follow-up**

Fifty patients did not respond at 12 months and were classified as lost to follow-up. Except for age and structural changes seen on MRI at the affected level of disc herniation, no significant differences existed between the full cases and those who were lost to follow-up.

**Success Rate**

At 12 months, 188 participants (75.8\%) were recovered based on GPE score; 144 participants (58.8\%) on disability, and 167 participants (67.3\%) on pain.

**Primary Outcome**

The final model for good recovery consisted of the following variables: younger age, higher intensity leg pain than back pain, a higher level of disability and a disc herniation at
### TABLE 1. Baseline Characteristics and Potential Prognostic Factors in Patients After Microdiscectomy (n = 298)

| Prognostic Factors                                      | N (%) or Mean ± SD |
|---------------------------------------------------------|--------------------|
| **Sociodemographic**                                    |                    |
| Female/Male                                             | 121 (40.6)/177 (59.4) |
| Age in years (SD)                                       | 44.9 (13.1)        |
| Educational level (low)*                                 | 50 (16.8)          |
| Comorbidity (yes)*                                      | 55 (18.5)          |
| **History**                                             |                    |
| Prior back surgery (yes)                                | 53 (17.8)          |
| Previous physiotherapy (yes)                            | 218 (73.2)         |
| Previous injection therapy (yes)                        | 50 (16.8)          |
| Preoperative medication use (yes)*                      | 59 (19.8)          |
| **Neurologic**                                          |                    |
| Straight leg raise test (positive)                       | 234 (69.7)         |
| **Symptoms**                                            |                    |
| Pain intensity back (VAS)*                              | 48.13 ± 29.6       |
| Pain intensity leg (VAS)*                               | 69.1 ± 22.7        |
| Leg pain > back pain (yes)*                              | 214 (71.8)         |
| Level of disability (RMDQ)*                             | 16.7 ± 3.9         |
| **Radiological**                                        |                    |
| Level of disc herniation                                |                    |
| L3–L4                                                   | 11 (3.7)           |
| L4–L5                                                   | 102 (34.2)         |
| L5–S1                                                   | 161 (54)           |
| More than one level                                     | 24 (8.1)           |
| Structural changes seen on MRI at the affected level of disc-herniation* | 121 (40.6)         |
| **Work**                                                |                    |
| Working status (yes)                                    | 267 (89.6)         |
| Sitting activities (yes)                                | 101 (33.9)         |
| Physical activities (yes)                               | 89 (29.9)          |

N indicates number of patients; %, percentage unless otherwise stated. Mean score ± standard deviation.

*Primary or basic education.

†Comorbidity, for example, diabetes, cardio-vascular disease, chronic obstructive pulmonary disease, hyperthyroid.

‡Preoperative medication use = over the counter or prescription medication.

§VAS indicates Visual Analogue Score (0–100 mm).

¶RMDQ indicates Roland Disability Questionnaire (0–24 points).

‖Structural changes on MRI at the affected level of disc-herniation = spinal stenosis, spinal cyst, facet arrosis, hyperplastic disc, or a combination.

another level than L3–L4 (Table 2). The variables for the model for poor recovery were low educational level, prior back surgery, and an L3–L4 disc herniation (Table 2).

The explained variance ($R^2$) was 0.06 for both models and the AUC was 0.63 for good recovery and 0.64 for poor recovery. After bootstrapping, the explained variance was 0.01 for good recovery and 0.02 for poor recovery, and the AUC was 0.58 for good recovery and 0.60 for poor recovery.

### Secondary Outcomes

The final model for no or minimal pain contained the following variables: a positive straight leg raise test, a low pain intensity score for the leg, and no structural changes seen on MRI at the affected level of disc herniation (Table 3). The final model for pain contained: previous pain management and structural changes seen on MRI at the affected level of disc herniation (Table 3). The explained variance ($R^2$) was 0.06 for no or minimal pain and 0.04 for pain. The AUC was 0.59 for no or minimal pain and 0.64 for pain. After bootstrapping, the explained variance was 0.00 (no or minimal pain) and 0.01 (pain). The AUC was 0.54 (no pain) and 0.59 (pain).

The final model for no or minimal disability contained six factors: younger age, positive straight leg raise test, low pain intensity score for the leg, higher intensity leg pain than back pain, lower level of disability, and sitting activities (Table 4). The model for disability also consisted of six factors: higher age, prior back surgery, medication, high pain intensity score for the back, a higher level of disability, and no sitting activities (Table 4). The explained variance ($R^2$) was 0.11 for no or minimal disability and 0.18 for disability. The AUC was 0.68 for no or minimal disability and 0.72 for disability. After bootstrapping, the explained variance was 0.05 (no disability) and 0.11 (disability), and AUC was 0.63 (no disability) and 0.69 (disability).

### DISCUSSION

This study aimed to develop and internally validate prognostic models based on demographic and biomedical data commonly captured preoperatively for the primary outcome recovery and the secondary outcomes pain and disability in patients who received lumbar microdiscectomy followed by physiotherapy. The derivation and internal validation revealed that none of the models was of sufficient performance to be considered for external validation and clinical use. We conclude that currently gathered preoperative data do not enable clinicians to predict outcomes of lumbar discectomy and postoperative physiotherapy accurately.

Our findings are in agreement with a previously derived model for lumbar discectomy.10 Comparable with our models, Cook et al used usual care data with low administrative and patient burden to predict clinical outcomes. The performance of these models was also poor with an explained variance ranging from 9% to 15%. Although these models were developed in a large dataset, prognostic factors were gathered retrospectively.

Besides usual care data, Ostelo et al7 included a limited number of psychosocial factors of which treatment expectancy and negative affectivity were associated with perceived recovery. The explained variance of these models ranged from 0.19% to 0.35%. Another study also found that psychosocial factors, such as passive pain coping and fear of movement/reinjury were associated with poorer outcome.8
One study used PROMIS scores in combination with clinical data. Promising is the use of a patient-reported outcome measurement information system (PROMIS) tool by computer adaptive testing to predict the outcome after lumbar microdiscectomy. When preoperative PROMIS scores on the domains’ physical function, pain interference, and depression were combined with clinical data, the ability to predict which patients were likely to improve clinically increased substantially with a discriminative ability of 0.83% to 0.87%. Though the effects were measured at 12 weeks follow-up, the sample size was small and evaluating outcomes with computer adaptive testing is not standard in clinical practice.

| TABLE 2. Final Model for Good and Poor Recovery at 12 Months (N = 298) |
|---------------------------------------------------------------|
| Predictor | OR (95% CI) | Beta | Adjusted Beta |
|-----------|-------------|------|--------------|
| Prognostic model for good recovery | | | |
| Age in years | 0.98 (0.95; 1.01) | -0.02 | -0.01 |
| Leg pain > back pain (yes) | 1.73 (0.89; 3.36) | 0.55 | 0.41 |
| Level of disability (RMDQ) | 1.09 (1.01; 1.19) | 0.09 | 0.07 |
| Disc herniation L3–L4 | 0.09 (0.02; 0.54) | -2.42 | 1.79 |
| Performance measures | Initial | | |
| Median R² (IQR) | 0.06 (0.05; 0.07) | 0.01 (0.00; 0.02) | 0.01 (0.00; 0.02) |
| Median AUC (IQR) | 0.63 (0.62; 0.64) | 0.59 (0.57; 0.60) | 0.59 (0.57; 0.60) |
| Prognostic model for poor recovery | | | |
| Educational level (low) | 2.23 (1.04; 4.77) | 0.80 | 0.58 |
| Prior back surgery | 1.92 (0.89; 4.18) | 0.65 | 0.47 |
| Disc herniation L3–L4 | 9.09 (1.56; 52.82) | 2.21 | 1.61 |
| Performance measures | Initial | | |
| Median R² (IQR) | 0.06 (0.06; 0.07) | 0.02 (0.02; 0.03) | 0.02 (0.02; 0.03) |
| Median AUC (IQR) | 0.64 (0.63; 0.65) | 0.59 (0.59; 0.60) | 0.59 (0.59; 0.60) |

*Regression coefficients multiplied by the shrinkage factor of 0.74 for good recovery (retrieved from bootstrapping procedure).
§Regression coefficients multiplied by the shrinkage factor of 0.73 for poor recovery (retrieved from bootstrapping procedure).

TABLE 3. Final Model for No or Minimal Pain and Pain at 12 Months (N = 298)

| Predictor | OR (95% CI) | Beta | Adjusted Beta |
|-----------|-------------|------|--------------|
| Prognostic model for no or minimal pain | | | |
| Straight leg raise test | 1.87 (0.96; 3.65) | 0.64 | 0.43 |
| Pain intensity leg (VAS) | 0.99 (0.98; 1.00) | -0.01 | -0.00 |
| Structural changes seen on MRI at the affected level of disc-herniation | 0.64 (0.36; 1.13) | -0.45 | -0.30 |
| Performance measures | Initial | | |
| Median R² (IQR) | 0.06 (0.05; 0.07) | 0.01 (0.00; 0.02) | 0.01 (0.00; 0.02) |
| Median AUC (IQR) | 0.64 (0.63; 0.65) | 0.59 (0.58; 0.60) | 0.59 (0.58; 0.60) |
| Prognostic model for pain | | | |
| Previous injection therapy | 2.02 (1.00; 4.07) | 0.70 | 0.41 |
| Structural changes seen on MRI at the affected level of disc-herniation | 1.56 (0.89; 2.72) | 0.45 | 0.27 |
| Performance measures | Initial | | |
| Median R² (IQR) | 0.04 (0.03; 0.55) | -0.01 (-0.01; -0.01) | -0.01 (-0.01; -0.01) |
| Median AUC (IQR) | 0.60 (0.58; 0.60) | 0.54 (0.53; 0.55) | 0.54 (0.53; 0.55) |

*Regression coefficients multiplied by the shrinkage factor of 0.67 for no or minimal pain (retrieved from bootstrapping procedure).
§Regression coefficients multiplied by the shrinkage factor of 0.59 for pain (retrieved from bootstrapping procedure).

95% CI indicates 95% confidence interval; AUC, area under the curve; IQR, interquartile range; OR, odds ratio; R², Nagelkerke R-squared.
Factors were a-priori selected based on previous systematic reviews which revealed at least moderate evidence for a univariable association with the outcomes. As not all factors were measured in the clinic where the study was conducted, it is reasonable that we could have missed some relevant factors. For example, the type of disc herniation is considered as an important factor. Unfortunately, this variable was not systematically recorded and we were not able to include this factor in our models.

Besides the importance of reconsidering several biomedical factors, it seems that models that consider a combination of biomedical and psychosocial data perform better than models developed with biomedical data solely. The literature also showed that psychological factors may have a strong association with the outcome after lumbar disc surgery. Prior to back surgery, ~67.0% of patients have some levels of psychological distress, and even ~25.0% have high levels of psychological distress. Nevertheless, only a minority (37%) of the clinicians collect psychological data. Moreover, when healthcare providers assess psychological factors, they usually rely on their subjective clinical impression instead of using validated and reliable instruments. Recent research has identified several suitable questionnaires for evaluating psychosocial factor, such as kinesiophobia, fear-avoidance, coping and distress in people with musculoskeletal pain, and also PROMIS measures are beneficial to use.

In conclusion, the outcome of lumbar microdiscectomy followed by physiotherapy cannot adequately be predicted by using routinely collected sociodemographic and biomedical data. Future research is needed to investigate the role of other biomedical, personal and external factors to potentially improve the prognostic ability for the outcome recovery, pain and disability. If good performing models can be derived in the future, internally and externally validation should appraise clinical usage.

**Key Points**

- Prognostic models based on commonly gathered sociodemographic and biomedical characteristics to predict the outcome of microdiscectomy followed by physiotherapy in patients with lumbar radiculopathy performed poorly and were not sufficient to be considered for external validation or clinical use.
- The performance of the derived models was comparable for the outcome recovery, pain and disability and all scored equally poorly.
- As currently gathered preoperative data do not predict outcome appropriately, other biomedical, personal and external factors have to be considered.

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**TABLE 4. Final Model for No or Minimal Disability and Disability at 12 Months (N = 298)**

| Predictor                          | OR (95% CI)       | Beta¹ | Adjusted Beta⁵ | Beta² | Adjusted Beta² | median R² (IQR) | median AUC (IQR) |
|-----------------------------------|-------------------|-------|----------------|-------|---------------|-----------------|------------------|
| Prognostic model for no or minimal disability |                   |       |                |       |               |                 |                  |
| Age in years                      | 0.98 (0.96; 1.01) | −0.02 | −0.01          |       |               |                 |                  |
| Straight leg raise test           | 1.76 (0.88; 3.52) | 0.57  | 0.42           |       |               |                 |                  |
| Pain intensity leg (VAS)          | 0.99 (0.97; 1.00) | −0.01 | −0.00          |       |               |                 |                  |
| Leg pain > back pain              | 1.63 (0.90; 3.20) | 0.49  | 0.36           |       |               |                 |                  |
| Level of disability (RMDQ)        | 0.92 (0.84; 1.00) | −0.09 | −0.07          |       |               |                 |                  |
| Sitting activities                | 1.93 (1.01; 3.67) | 0.66  | 0.48           |       |               |                 |                  |
| Performance measures              | Initial Bootstrap  |       |                |       |               |                 |                  |
| Median R² (IQR)                   | 0.11 (0.09; 0.13) | 0.05  | 0.06           |       |               |                 |                  |
| Median AUC (IQR)                  | 0.67 (0.66; 0.69) | 0.63  | 0.64           |       |               |                 |                  |
| Prognostic model for disability   |                   |       |                |       |               |                 |                  |
| Age in years                      | 1.03 (1.00; 1.05) | 0.03  | 0.02           |       |               |                 |                  |
| Prior back surgery                | 2.80 (1.34; 5.88) | 1.03  | 0.81           |       |               |                 |                  |
| Preoperative medication use        | 1.99 (1.01; 3.94) | 0.69  | 0.55           |       |               |                 |                  |
| Pain intensity back               | 1.01 (1.00; 1.02) | 0.01  | 0.00           |       |               |                 |                  |
| Level of disability (RMDQ)        | 1.08 (0.98; 1.18) | 0.08  | 0.06           |       |               |                 |                  |
| Sitting activities                | 0.58 (0.31; 1.11) | −0.54 | −0.43          |       |               |                 |                  |
| Performance measures              | Initial Bootstrap  |       |                |       |               |                 |                  |
| Median R² (IQR)                   | 0.18 (0.16; 0.18) | 0.11  | 0.13           |       |               |                 |                  |
| Median AUC (IQR)                  | 0.72 (0.72; 0.73) | 0.69  | 0.70           |       |               |                 |                  |

¹P-value < 0.05.
²Regression coefficients multiplied by the shrinkage factor of 0.73 for no or minimal disability (retrieved from bootstrapping procedure).
³Regression coefficients multiplied by the shrinkage factor of 0.79 for disability (retrieved from bootstrapping procedure).
⁴Performance measures acquired from bootstrapping procedure.
⁵Performance measure acquired from bootstrapping procedure.
⁶95% CI indicates 95% confidence interval; AUC, area under the curve; IQR, interquartile range; OR, odds ratio; R², Nagelkerke R-squared.
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