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A multivariate prognostic model for pain and activity limitation in people undergoing lumbar discectomy

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ABSTRACT

Purpose: The purpose of this study was to identify a multivariate predictive model for 6-month outcomes on overall pain, leg pain and activity limitation in patients undergoing lumbar discectomy. Identification of predictors of outcome for lumbar discectomy has the potential to assist identifying treatment targets, clinical decision making and disease understanding.

Materials and methods: Prospective cohort design. Ninety-seven patients deemed by study surgeons to be suitable for lumbar discectomy completed a comprehensive clinical and radiological baseline assessment. At 6-months post surgery outcome measures of overall and leg pain (visual analogue scale) as well as activity limitation (Oswestry Disability Index) were completed. Univariate and multivariate analyses were conducted to determine the best multivariate predictive model of outcome.

Results: In the multivariate model, presence of a compensation claim, longer duration of injury and presence of below knee pain and/or parasthesia were negative prognostic indicators for at least two of the outcomes. Peripheralization in response to mechanical loading strategies was a positive prognostic indicator for overall pain and leg pain. A range of other prognostic indicators for one outcome were also identified. The prognostic model explained up to 32% of the variance in outcome.

Conclusions: An 11-factor prognostic model was identified from a range of clinically and radiologically assessed variables in accordance with a biopsychosocial model. The multivariate model has potential implications for researchers and practitioners in the field. Further high quality research is required to externally validate the prognostic model, evaluate effect of the identified prognostic factors on treatment effectiveness and explore potential mechanisms of effect.

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Lumbar radiculopathy; prognosis; discectomy; prospective; cohort

Introduction

People with lumbar disc herniation and associated radiculopathy (DHR) have poorer outcomes and higher healthcare costs than those with back pain alone.^{1,2} Discectomy for DHR is recommended in clinical guidelines³ however evidence from recent systematic reviews is conflicting.^{4,5} There are significant risks associated with lumbar discectomy⁶ as well as evidence of increased rates of surgical treatment despite no change in prevalence of DHR over recent years.⁷

Identification of prognostic factors is important in people with DHR to inform/educate on likely outcomes and generate hypotheses that aid future research into understanding disease processes.^{8–11} Prognostic factors can also assist in identifying risk groups of potential relevance as treatment targets for improving treatment effectiveness.^{11–13} For example if older age is identified as a negative prognostic factor for pain and disability in DHR, relevant patients can receive specific education and treatment decision making may be modified.

Systematic reviews on prognostic factors for people undergoing discectomy for DHR have identified significant methodological shortcomings and limited evidence.^{11,14,15} To the best of our knowledge there are no high-quality studies evaluating a

range of biomedical and psychosocial prognostic factors using multivariate methods in people undergoing lumbar discectomy.

The aim of this study was therefore to develop a multivariate prognostic model for change in overall pain, leg pain and activity limitation based on clinical and radiological features for people with DHR receiving lumbar discectomy.

Methods

Study population

The study was approved by the University of Melbourne (HREC number 040634), Human Research Ethics Committee. Eleven orthopedic surgeons and neurosurgeons from the Epworth and Freemasons Hospitals in Victoria, Australia participated in the study. Potential patients for the study were identified from those booked for lumbar discectomy. There was contact with each patient to explain the study, assess eligibility criteria and seek informed consent where applicable.

Eligible patients were literate in spoken and written English, had undergone magnetic resonance imaging (MRI) of the lumbar spine in the past 6-months and were booked in for lumbar discectomy. Patients were excluded if they had computerized

tomography scan or MRI confirmed central or lateral canal stenosis, spondylolisthesis/spondylosis or symptoms due to non-mechanical pathology (i.e. tumor, infection, inflammatory arthritis) or previous surgery to the lumbar spine.

Prognostic factors

All patients underwent a comprehensive and standardized clinical assessment (Supplementary material – Online Resource 1) as well as review of recent MRI scan before undergoing discectomy which provided data on potential prognostic factors.

Sociodemographic factors

Information was recorded regarding age, gender, smoking habits and existence of a compensation claim related to the DHR.¹⁶

Low back pain-related subjective examination

A reliable and valid questionnaire for subjective examination was used to record data on: duration, location and nature of symptoms, pain drawing, aggravating and easing factors and history of symptoms.¹⁶

Low back pain-related physical examination

A range of valid and reliable physical examination items¹⁷ was measured including: active movement testing, straight leg raise, crossed straight leg raise, provocative sacro-iliac joint testing, lower limb neurological examination, response to mechanical loading strategies and lumbar palpation.¹⁸ Mechanical loading strategies comprised sustained or repeated extensions while lying prone which have been shown to impact on the position of the nucleus pulposus in relation to the annulus fibrosis and the lumbar nerve roots.^{19–21} Patient response was scored as either no effect, centralization (involving the proximal migration and/or abolition of distal symptoms originating from the spine) or peripheralization (the opposite response of centralization where distal symptoms were increased).²²

Psychosocial risk factors

The Örebro Musculoskeletal Pain Questionnaire²³ is a valid and reliable self-administered questionnaire that was used to evaluate risk of poor outcome due to psychosocial factors including activity

limitation, psychological distress (e.g. depression and anxiety), recovery expectations, job satisfaction and fear avoidance beliefs.²⁴ Non-organic signs were also tested as a measure of symptom amplification.²⁵

Magnetic resonance imaging (MRI)

Potential radiological prognostic factors were measured by a study radiologist, blinded to the baseline clinical assessment/patient outcomes, who assessed the patient's MRI scan using a standardized protocol. The four reported radiological criteria were type of herniation, presence/degree of nerve root contact, presence/degree of annular fissure and spinal canal compromise caused by the herniation. These criteria are important when reporting on disc herniation and have demonstrated reliability.^{26,27} The rating system used by the radiologist is summarized in Table 1.

Composite items

Given the complexity and multi-factorial nature of low back disorders,²⁸ composite items may be more likely to be clinically meaningful and prognostic. We, therefore, derived composite items for clinical radiculopathy ± nerve root compression ± distal symptoms most severe (as each of these features plausibly increases the likelihood of symptomatic DHR that would be responsive to surgery) as well as clinically diagnosed discogenic pain²⁹ without clinical radiculopathy (as such cases would be plausibly not suitable for discectomy).

Outcome measures

Self-administered standardized outcome measures were completed by patients at baseline assessment and at 6-month post-surgery. These included valid and reliable measures of activity limitation (Oswestry Disability Index^{30,31}) and visual analog scale^{32,33} as measures of overall pain (VAS_{ALL}) and leg pain (VAS_{LEG}). These outcomes were selected as literature on effectiveness of discectomy for different outcomes is variable^{4,5} and people with DHR commonly experience back pain, leg symptoms and significant activity limitation.

Table 1. Assessment criteria for magnetic resonance imaging scans.

Feature	Definition (please circle clearly)
Herniation type ¹⁹	<p>Normal</p> <p>Broad-based – involving 25–50% (90–180°) of the disc circumference</p> <p>Focal – involving < 25% (< 90°) of the disc circumference</p> <p>Protrusion – when the diameter of herniation is greatest at the base</p> <p>Extrusion – where the diameter of herniation at the base is smaller than at the widest diameter</p> <p>Sequestration – where the herniated material is detached from intervertebral disc</p>
Nerve root contact ²⁰	<p>Normal – showing no evidence of contact of disc material with the nerve root and where the epidural fat layer between the nerve root and the disc is preserved</p> <p>Contact – showing visible contact of disc with the nerve root (without dorsal deviation) and where the normal epidural fat layer not evident</p> <p>Deviation – where the nerve root is displaced dorsally by disc material</p> <p>Compression – where the nerve root is compressed between disc material and wall of spinal canal; it may appear flattened or indistinguishable from the disc</p>
Annular fissure	<p>Intact</p> <p>Mild fissure</p> <p>Severe fissure</p>
Canal compromise ¹⁹	<p>Mild – < 1/3 of the canal compromised</p> <p>Moderate – 1/3–2/3 of the canal compromised</p> <p>Severe – > 2/3 of the canal compromised</p>

Surgical procedure

The study surgeons had an average of 10-years experience in spinal surgery in major private and public teaching hospitals in Australia and overseas and regularly performed discectomy as part of their clinical practice. All surgeons performed discectomy according to their standard procedures. Any variation in techniques employed by surgeons was not expected to have an effect on outcome as comparable outcomes have been consistently reported with microdiscectomy compared to discectomy.³⁴ In all cases, the surgical procedure was performed with the aim of removing the portion of the intervertebral disc adjacent to the affected nerve root, considered to be the cause of radiculopathy.

Statistical analysis

In order to explore 10 potential prognostic factors based on a requirement for 10 patients per variable³⁵, a sample size of 100 patients was required. We allowed for a loss to follow up of 10% and, therefore, recruitment of 110 patients was planned a priori.

A multi-phase data analysis³⁶ was completed with phase 1 comprising a univariate analysis to determine which baseline factors were prognostic for activity limitation and pain outcomes at 6-month. Each potential prognostic factor was evaluated by the applicable univariate test of association with each outcome using Minitab Statistical Software version 15 (Minitab, Inc., State College, PA, USA). Potential predictors measured on ordinal and interval scales were evaluated using Pearson's correlation coefficient. The outcome measures of Oswestry, VAS_{LEG} and VAS_{ALL} were treated as continuous data. The purpose of these univariate analyses was to identify the 10 predictors with the most significant association (lowest *p* value) with change scores in the outcome measures of interest. There was, therefore, no predetermined *p* value level of significance.

Table 2. Baseline patient characteristics (*N* = 97).

Characteristic	
Demographics	
Age, mean (SD) years	45.2 (12.9)
Female, number (%)	30 (31%)
Surgery covered under a 3rd party compensation scheme	26 (27%)
Duration of symptoms	
< 3 months	39 (40%)
3–12 months	37 (38%)
> 12 months	21 (22%)
At least one neurological sign	91 (94%)
Positive straight leg raise test	83 (86%)
Magnetic resonance imaging intervertebral disc contour	
Disc bulge	3 (3%)
Disc protrusion	32 (33%)
Disc extrusion	53 (55%)
Disc sequestration	5 (5%)
Magnetic resonance imaging nerve root involvement	
Nerve root deviation	15 (16%)
Nerve root compression	75 (78%)
Level of surgery	
L4/5	41 (42%)
L5/S1	56 (58%)

Table 3. Overall outcomes to discectomy/microdiscectomy.

Outcome measure	Baseline mean (SD)	6 months follow up mean (SD)	Mean change (SD); 95% CI
Oswestry	41.4 (17.0)	19.9 (18.6)	–21.5 (21.7): –17.1 to –25.9
VAS _{LEG}	6.7 (2.2)	2.9 (2.9)	–3.9 (3.3): –3.2 to –4.5
VAS _{ALL}	6.0 (2.6)	2.7 (2.7)	–3.3 (3.4): –2.6 to –4.0

SD: standard deviation; CI: confidence intervals.

Phase 2 comprised multivariate analysis to explore the contribution of individual factors to a prognostic model taking into account potential between-factor interaction.^{35,37} The aim of the model was to identify the combination of factors that was optimally prognostic for change in outcome scores from baseline to 6-month. Best subsets regression was used to determine the best multivariate model given that stepwise procedures are not guaranteed to find the best fitting model when a set number of predictors is specified.^{37,38} The best two factor, three factor, four factor model and so on was determined using best subsets regression. Standard linear regression entering the predictive variables from each of the best models from the best subsets regression was conducted to obtain *p* values for the individual predictor within that model. A significance *p* value of less than .05 was selected to test if each individual variable was an independent contributor to the linear model. In determining the best overall model with the largest number of predictors making a statistically significant unique contribution to the model was selected. If two models with a different number of predictive variables had the same number of statistically significant predictors, the model with the fewer number of predictors was preferred, on the grounds of parsimony.³⁷ The proportion of variance in outcomes attributable to the model^{39,40} was assessed by generation of 'adjusted R-square' values derived using linear regression.

Results

Preceding lumbar discectomy, 110 potential participants were identified and contacted. Two patients cancelled their surgery and one declined completion of the baseline assessment. One hundred and seven consenting patients underwent lumbar surgery with four undergoing procedures that did not involve removal of disc tissue. Two further patients did not complete the follow-up outcome measures due to personal reasons for one and an extended holiday overseas for the other. Four patients underwent repeat discectomy. These six cases were also excluded from the analysis leaving a total of 97 patients included in the analysis.

Baseline patient characteristics are presented in Table 2.

When measuring baseline function and pain, the participants had mean (SD) Oswestry scores of 42 (17.6) percent with VAS_{LEG} scores of 5.7 (2.7) and VAS_{ALL} scores of 6.0 (2.6). Baseline Orebro scores showed a mean (SD) of 117.5 (24.9) out of a possible 210 indicating a significantly increased risk of poor outcome due to psychosocial factors.⁴¹

Mean (SD) changes in outcome measure scores from baseline to 6-month post-surgery were 3.3 (3.4) mm for VAS_{ALL}, 3.9 (3.3) mm for VAS_{LEG} and 21.5% (21.7%) for Oswestry. These data are presented in Table 3.

Ten potential prognostic factors were evaluated based on univariate *p* values of association with each outcome measure (Table 4). Results for univariate analyses of all potential prognostic factors are available in Supplementary material – Online Resource 2. The presence of below knee pain or paresthesia and a longer duration of symptoms were negative prognostic factors for each outcome measure. Worsening of symptoms in response to mechanical loading

Table 4. Univariate analysis of potential predictors to discetomy.

Change in Oswestry	N	r ²	p Value	Change in VAS _{LEG}	N	r ²	p Value	Change in VAS _{ALL}	N	r ²	p Value
Duration of symptoms (-)	97	0.101	.001	Duration of symptoms (-)	97	0.078	.006	Compensation (-)	96	0.081	.005
Reduced walking tol. (+)	97	0.091	.003	Worse sustained/repeated EIL (+)	95	0.067	.012	Below knee pain/paresthesia (-)	97	0.052	.025
Getting to sleep difficult (+)	97	0.084	.004	Oswestry (+)	97	0.046	.035	Worse sustained EIL (+)	93	0.062	.016
Reduced supported sitting tol. (+)	96	0.079	.006	Reduced supported sitting tol. (+)	96	0.045	.037	VAS back pain ^ (+)	97	0.049	.029
Worse sustained/repeated EIL (+)	95	0.069	.010	At least one night symptom (+)	97	0.037	.058	VAS leg pain baseline (+)	97	0.048	.031
Below knee pain/paresthesia (-)	97	0.052	.026	Nerve root compression MRI (+)	88	0.039	.064	Non-focal palpation (-)	95	0.039	.055
First episode of symptoms (-)	97	0.052	.026	Non focal palpation (-)	95	0.034	.074	Symptom onset composite (-)	97	0.047	.033
Contralateral SLR sensitization (-)	97	0.042	.045	VAS back pain (+)	97	0.027	.110	Duration of symptoms (-)	97	0.033	.074
Compensation (-)	96	0.041	.049	Distal > proximal pain (+)	96	0.027	.110	Oswestry (+)	97	0.032	.078
Reduced standing still tol. (+)	97	0.038	.055	Below knee pain/paresthesia (-)	97	0.023	.135	Focal palpation (+)	95	0.029	.098

(-) indicates a predictor of less favorable change in follow up outcome measures compared to baseline; (+) indicates a predictor of more favorable change in outcome measures compared to baseline; tol.: tolerance; EIL: extension in lying; VAS: visual analog scale; Sum of night symptoms: composite score on night symptoms; MRI: magnetic resonance imaging; SLR: straight leg raise; ^ VAS back pain was a severity of pain score measured as part of the Subjective Complaints Questionnaire and was separate to the VAS outcome measure.

Table 5. Final multivariate models for prediction of discetomy outcome.

Change in Oswestry N = 95	Beta	95% CI	p Value	Change in VAS _{LEG} N = 94	Beta	95% CI	p Value	Change in VAS _{ALL} N = 92	Beta	95% CI	p Value
Constant	-44.3	-58.6, -30.0	.000	Constant	-4.7	-6.3, -3.1	.000	Constant	-4.3	-6.8, -1.8	.001
Below knee pain/paresthesia (-)	18.4	5.9, 30.9	.005	Worse sustained repeated EIL (+)	-1.6	-2.8, -0.4	.013	Compensation status (-)	2.2	0.8, 3.6	.003
Getting to sleep difficult (+)	-13.0	-22.0, -4.0	.006	Duration symptoms (-)	0.6	0.2, 1.0	.007	VAS back pain ^ (+)	-0.4	-0.7, -0.1	.011
Contralateral SLR sensitization (-)	10.7	2.9, 18.5	.008	R-squared				Below knee pain/paresthesia (-)	2.4	0.3, 4.5	.024
Duration of symptoms (-)	3.3	0.7, 5.9	.014					Worse sustained EIL (+)	-1.4	-2.7, -0.1	.043
Compensation status (-)	10.5	2.1, 18.9	.017					Non-focal palpation (-)	1.2	0.1, 2.3	.043
Reduced supported sitting tol. (+)	-4.2	-7.6, -0.8	.018					R-squared	0.23		
R-squared	0.32										

(-) indicates a predictor of less favorable change in follow up outcome measures compared to baseline; (+) indicates a predictor of more favorable change in outcome measures compared to baseline; tol.: tolerance; EIL: extension in lying; VAS: visual analog scale; SLR: straight leg raise; ^ VAS back pain was a severity of pain score measured as part of the Subjective Complaints Questionnaire and was separate to the VAS outcome measures.

strategies was a positive prognostic factor for each outcome measure.

Table 5 shows the best statistical models as determined by multivariate analysis of the 10 prognostic factors from the univariate analysis. The best model for change in outcomes was a six variable model for Oswestry scores, a two-variable model for VAS_{LEG} and a five variable model for VAS_{ALL}. Four variables predicted outcome across more than one outcome measure being compensation status, duration of symptoms, below knee pain or paresthesia (all negative prognostic factors) and being worse with the mechanical loading strategies of sustained or repeated extension in lying (positive prognostic factor).

Discussion

This study identified a prognostic model from a range of biomedical and psychosocial measures for people with lumbar DHR undergoing discectomy. The multivariate model explained 12–32% of the variance depending on the outcome evaluated. Prognostic factors are useful in providing patients with a given condition and their clinicians specific information relevant to decision making.^{11,42} Our results also provide important information relevant to exploring treatment targets and improving treatment outcomes for future research.

Compensation status was found to be associated with less favorable outcomes on Oswestry and VAS_{ALL} following lumbar discectomy. These findings support previous research for patients undergoing spinal surgery⁴³ and those sick listed due to recent onset back pain.⁴⁴ Worse outcomes for patients with a compensation claim may be due to incentive related psychological and social factors.^{43,44}

A longer duration of symptoms was associated with a less favorable outcome to discectomy as measured by change in Oswestry and VAS_{LEG} consistent with previous studies.⁴⁵ It has been proposed that prolonged nerve root irritation caused by a disc herniation may lead to permanent functional impairment of the nerve root⁴⁶ and a less optimal response to surgical intervention. Alternatively, it may be that psychosocial factors commonly associated with a longer duration of symptoms^{47–49} accounted for the significance of this prognostic factor in our results. However, it should be noted that no psychosocial factors analyzed in our study had sufficient prognostic value to be included in the multivariate model making this a less likely explanation.

Below knee pain and/or paresthesia is a key component in diagnosing lumbar radiculopathy and is important information in determining the need for lumbar discectomy.⁵⁰ It was, therefore, an interesting finding that below knee pain and/or paresthesia was a predictor of a less favorable response to discectomy as measured by change in Oswestry and VAS_{ALL}. A recent systematic review¹¹ identified six studies investigating leg symptoms as a prognostic factor and concluded that further low risk of bias studies were required due to the low quality of the findings. The results from our high methodological quality study suggest that further research is required into the prognostic relevance of, and mechanisms underpinning, leg symptoms in relation to lumbar discectomy.

The McKenzie approach is a commonly used method of managing low back disorders with a key focus on evaluating clinical response to mechanical loading strategies including centralization or peripheralization of symptoms.⁵¹ Such patients may be responsive to conservative treatment based on the preferential mechanical loading strategy, which is commonly adoption of

postures, movements and exercises facilitating lumbar extension rather than flexion.^{20,21} There is substantial evidence suggesting a response to mechanical loading strategies is a relevant prognostic indicator in people with back pain.⁵² However to the best of our knowledge this has not been investigated in a high quality prospective study of people with DHR undergoing lumbar discectomy.

Our results showed that peripheralization of symptoms (that is worsening) in response to repeated or sustained extension in lying was a positive prognostic factor for VAS_{LEG} and VAS_{ALL}. The centralization/peripheralization phenomenon is thought to be a result of mechanical loading strategies, influencing the hydrostatic properties of the lumbar intervertebral disc by applying a 'reductive force' to displaced intervertebral disc material.²⁰ In patients with DHR particularly with associated extrusion or sequestration, an incompetent/disrupted outer wall of the annulus fibrosus may prohibit this hydrostatic mechanism (analogous to trying to squeeze toothpaste back into a broken tube). In such patients, lumbar extension may facilitate further posterior migration of nuclear material, increased nerve root compromise and resultant peripheralization of symptoms.⁵³ This mechanism underpinning peripheralization as a positive prognostic indicator fits with observations of disc extrusions or sequestrations being more responsive to lumbar discectomy.⁵⁴

A number of other variables were shown to be prognostic for one of the outcome measures including positive provocation of leg symptoms in response to sensitization during contralateral straight leg raise (predicting a less favorable outcome on Oswestry), higher VAS back pain at initial assessment (predicting a more favorable outcome on VAS_{ALL}), difficulty getting to sleep (predicting a more favorable outcome on Oswestry), decreased sitting tolerance (predicting a more favorable outcome on Oswestry) and non-focal palpation (predicting a less favorable outcome on VAS_{ALL}). A variety of mechanisms including severity of disc herniation, inflammatory influences, the mechanics of discogenic injury and symptom amplification could be hypothesized as explanations for these findings.

Demographic and psychological factors commonly associated with poor prognosis in patients undergoing lumbar discectomy, such as age and psychological distress³ were not found to be independent prognostic factors within the context of a comprehensive multivariate model. Few high quality studies have evaluated a range of potential prognostic factors representative of the biopsychosocial model of illness. It may be that in such a context demographic and psychological factors are less relevant to prognosis than previously thought.

Our results combined with the existing literature on low back disorders suggest the impact of the above described prognostic variables should be considered for further investigation in adequately powered randomized controlled trials involving lumbar discectomy as one treatment arm. Such a study design is most appropriate to determine whether the factors in our prognostic model are associated with a negative or positive outcome relative to a comparison treatment.⁴²

Much of the research on prognostic factors for LBP has been reported to be of low quality.¹⁴ The strengths of this study include selection of a prospective, clearly defined and representative sample, low loss to follow-up, use of predominantly reliable and valid measures of prognosis/outcomes, use of a range of factors representative of a biopsychosocial approach within a multivariate model and appropriate statistical analysis.⁵⁵

Study limitations

There are some limitations including insufficient validation for some measures used as potential prognostic factors. Although we measured the psychosocial domain using a well-accepted screening tool,⁴¹ it is possible that a larger amount of variance due to psychological factors would have been explained by more specific diagnostic measures.

Further research is required to validate our model in an alternative data set.⁵⁶ Adequately powered, prospective randomized controlled trials would also be of value to evaluate the interaction between time, intervention and prognostic factors.⁴²

Conclusions

An 11-factor prognostic model was identified from a range of clinically and radiologically assessed variables in accordance with a biopsychosocial model. These data and the potential mechanisms underpinning the model provide evidence confirming the importance of prognostic factors including duration of symptoms and presence of a compensation claim. A range of other prognostic factors were identified of potential relevance to researchers and practitioners with reference to validating and providing individualized treatment for people with DHR. Clinicians in the field should consider these factors when providing patient education and with reference to clinical decision making. Further high-quality research is required to externally validate the prognostic model, evaluate effect of the identified prognostic factors on treatment effectiveness and explore potential mechanisms of effect.

Disclosure statement

No potential conflict of interest was reported by the authors.

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