

The risk of “getting worse” after lumbar microdiscectomy

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Abstract A frequent concern among patients operated for lumbar disc herniation is the risk of “getting worse”. To give an evidence-based estimate of the risk for worsening has been difficult, since previous studies have been more focused on unfavourable outcome in general, rather than on deterioration in particular. In this prospective study of 180 patients, we report the frequency of and the risk factors for getting worse after first time lumbar microdiscectomy. Follow-up time is 12 months. Primary outcome measure was the Oswestry Disability Index, assessing functional status and health related quality of life. Four percent of the patients got worse. Independent risk factors for deterioration were a long duration of sick leave and a better functional status and quality of life prior to operation. We conclude that the risk for deterioration is small, but larger if the patient has been unable to work despite relative small health problems. This study also demonstrates that changes in instrument scores should be reported, so that an accurate failure rate can be assessed.

Key words lumbar discectomy • outcome • failed back • prognostic factors

Introduction

Lumbar microdiscectomy is the most frequently performed spinal operation. A frequent concern among the patients is the risk for “getting worse” after the operation. It is difficult to give an evidence-based estimate of the risk for deterioration, since previous studies have been more focused on unfavourable outcome in general, rather than on deterioration in particular. Some studies report on increase in pain after microdiscectomy [17, 26, 29]. One study reported on decrease in health related quality of life (HRQL) after such operations [30]. Prospective studies focusing on deterioration of functional status after microdiscectomy are lacking.

Several predictors for an unfavourable outcome have been identified [1, 2, 12, 20, 25, 28, 30-32] and socio-economic and psychological factors seems to play a major role [7, 9, 15, 21, 24]. Risk factors for deterioration of functional status and HRQL after microdiscectomy have not been reported. Furthermore, patients with a favourable outcome score at follow-up may have deteriorated, but this only becomes evident when the change in score is considered. This implies that risk factors for deterioration and a “poor outcome” might be different.

The aim of this prospective study is to evaluate predictors for and the frequency and significance of “getting worse” in a cohort of 180 patients operated with microdiscectomy for lumbar disc herniation.

Materials and methods

Patient population

This study comprises all patients operated with microdiscectomy at the Department of Neurosurgery at the University Hospital of North Norway from 1st of January 2000 to 1st of June 2003. Data were collected in a comprehensive registry intended for research and quality control. Only patients operated for one level lumbar disc herniation, affecting one nerve root, and who had been to 12 months follow-up evaluation were included. Patients who had undergone low back surgery previously were excluded.

Out of 228 consecutive patients, 180 were included (Figure 1). Thirty-six patients (15.7%) were lost to follow-up.

Informed consent was obtained from all participants and the Regional Ethical Committee for Medical Research approved the design of the study. The Data Inspectorate in Norway approved the registration and management of data.

Outcome measurement

We used the Oswestry Disability Index (ODI) as main outcome measure. The change in ODI score between baseline and 12 months after operation was classified as “deterioration” (increased ODI score) or “no deterioration” (decreased or unchanged ODI score). The ODI raw score at 12 months after operation was classified as “poor” (ODI score >39) or “good” (ODI score <40). Secondary outcome measures were employment status, back and leg pain.

Questionnaires

The questionnaires listed below were completed by the patients at admission for surgery and 12 months after the operation.

Functional status was assessed by the Oswestry Low Back Disability Questionnaire [10], which contains 10 questions on limitations of activities of daily living. Each variable is rated on a 0–5 point scale, added up and transferred into a percentage score, the ODI [3]. The range of possible values is from 0 (best health state) to 100 (worst health state). The ODI is also used as a disease-specific measure of HRQL [22].

Pain intensity was graded in two separate 100-mm visual analogue scales for back (VAS back) and leg (VAS leg) pain, endpoints being no pain and worst conceivable pain.

Anxiety and depression were valued on a three level scale where patients could indicate if they had no, moderate or severe problems.

Clinical data

At admission for surgery, a doctor collected the clinical data. Follow-up data were recorded by an independent observer (trained nurse) at an outpatient clinic.

Clinical examination included a straight leg raising (SLR) test and three indicators of neurological deficits (muscle atrophy, muscle strength and sensory impairment to pinprick). The result of each evaluation was rated on a three-step scale including no, moderate and severe impairment.

Surgical Procedure

A standard microdiscectomy was performed using Caspar self-retaining retractors and an operating microscope.

Statistical analyses

Differences in means were evaluated by students t-tests. To assess risk factors, we used linear and logistic regression models. In multivariate analyses, we identified statistically significant risk factors by stepwise regression. All statistical analyses were calculated in the Statistical Package for the Social Sciences (SPSS for Windows, version 10.0, Chicago IL).

Effect size (ES) was estimated according to the method of Kazis et al. [16]. ES is the difference between pre-treatment and post-treatment scores divided by the standard deviation of the pre-treatment score, and indicates the relative size of the effect in comparison to underlying “noise” of the data [4]. An ES of 0.8 or more is considered to be large [5].

Results

Characteristics of the study population

Mean (SD) age was 41 (11) years and 66 (36.7%) of the patients were females. Forty-nine percent were smokers. Mean (SD) body mass index, BMI, was 26.2 (9.0). The mean (SD) duration of sick leave prior to operation was 19.4 (25.4) weeks. Minimal level of primary school had been completed by 25%, technical or general college by 47% and university or high school by 28% of the patients.

A positive straight leg raising (SLR) test below 60 degrees elevation was found in 72 %, motor weakness in 42% and sensory deficits in 77% of the cases. Fifty-three percent of the patients were operated at the L5/S1 level, 41% at L4/L5 and 6% at the L3/L4 level.

Seven patients (3.9%) had complications to the operation. There were two cases of postoperative discitis and two cases of superficial wound infections. One postoperative muscle-

hernia was closed surgically several weeks after the microdiscectomy. One dural tear was repaired during the primary operation. One subcutaneous postoperative hematoma was treated non-surgically. The ODI score had increased in only one of these cases (superficial wound infection) at twelve months. There was no mortality.

Outcome assessments

Characteristics about employment status are listed in Table 1. Out of 134 sick listed patients, 92 % were on full and 8 % were on part time sick leave at baseline. At 12 months, 88 (65.7 %) of them had returned to full employment, 6 (4.5 %) could only work part time and 15 (11.2 %) were still unable to work.

Mean (SD) percent improvement of preoperative ODI score was 68.5 % (34.2.) ES was large (Table 2). Seven patients (3.9%) had a worsening of functional status as measured by an *increase* in ODI score. Their characteristics are listed in table 3. A change of 10% in the ODI score is considered to be clinically relevant [2, 13, 27]. Six of these patients were evaluated with postoperative contrast-enhanced MRI scans. One patient (Male 39 years) refused. Only normal postoperative changes were found. There were no signs of recurrent disc herniation, spondylodiscitis, spinal stenosis or spondylolistesis. All of them were regarded as failure cases according to the medical records and were evaluated by a neurosurgeon. Two patients had neuropathic nerve root pain, the others were considered to have unspecific back pain. Additional muscular involvement and referred pain is described as myofascial back pain in table 3. None had been offered further surgery when this study was closed.

Twelve patients (6.7%) had a “poor” outcome as measured by an ODI raw score >39 at 12 months follow-up. Only three (43 %) out of the seven patients who had a deterioration in ODI score also had a “poor” ODI score at follow-up.

Risk factor analyses

The linear regression analyses showed that a longer duration of sick leave (weeks) ($\beta = 0.128$, $P = 0.002$) and a lower ODI score ($\beta = -0.811$, $P < 0.001$) prior to operation are strong predictors for less improvement in ODI score among all 180 cases. (R squared (R^2) = 0.71)

When using the change in ODI score as a dichotome variable (no deterioration or deterioration) in age-adjusted regression analyses, we found three possible predictors for an increase in ODI score. Patients who deteriorated had a significant lower ODI score prior to operation, had been on sick leave for more weeks and had endured more weeks of leg pain prior to operation, compared to those who improved (Table 4).

Only a low ODI score and a longer duration of sick leave prior to operation were independent risk factors for deterioration. Other cofactors evaluated in the model (expectations, anxiety and depression and clinical parameters) were not significant.

We also used the ODI raw score at 12 months as a dichotome variable (“good” or “poor outcome) in multivariate analyses as described above. The only independent risk factor for a “poor” outcome (ODI score > 39) was long duration of sick leave ($\beta = 0.20$ $p = 0.026$) prior to operation.

Discussion

This study shows that 4 % of the patients have a worsening of the functional status and HRQL after lumbar microdiscectomy. The deterioration is significant, and it occurs within a larger cohort of patients with a favourable overall outcome, similar to results published elsewhere [2, 9, 17, 21, 25, 26]. Patients who have been sick-listed for a longer period of time or have a better ODI score prior to operation are at higher risk for “getting worse”. Thus, this study confirms what most surgeons would suspect, namely that the potential for deterioration is greater among patients with less severe health problems. Operative complications do not seem to play an important role for deterioration.

Evaluation of risk factors linked to such a small proportion of the study population should be done with caution. However, the same predictors also had a strong negative impact ($R^2 = 0.71$) on the outcome of all the patients, regardless of whether they had got worse or not. We therefore consider these risk factors to be clinically relevant.

Assessment of pain, work status and functional score are regarded as the most dependable instruments in outcome research, but they are not interchangeable [8]. They represent different aspects of outcome, measure different failure rates [14], and identify different prognostic factors [6, 30]. There is also a shift of patients between different outcome groups during the postoperative observation period. A patient with a good outcome after 3 months may have a poor result after one year. As a consequence, prognostic factors may change during the follow-up period [31], even though the overall outcome seems to be stable over the course of time [11].

Since the ODI is a well validated, reliable and a responsive measure of functional score and HROL [7, 22], we chose improvement or deterioration in ODI score as the category variable

in our analyses. Moreover, functional well being and better quality of life would be optimal therapeutic goals for the patients [18, 33].

It is reasonable to regard a final ODI score > 39 as a “poor result” since the surgery has failed to relieve a severe functional status. If we add the patients who got worse despite a raw score < 40 , the failure rate increases from 12 (6.7 %) to 16 (8.9 %) Patients who have to be reoperated can also be classified as failures. If we add the seven cases that were excluded because of recurrent disc herniation, the failure rate is 23 (12.3 %).

Hence, to avoid underestimating of the failure rate, a prospective study should identify patients who deteriorate by evaluating score *changes* [23]. These methodological problems are encountered in retrospective studies and studies that despite a prospective design, only report follow-up data, i.e. outcome scores. Furthermore, one should clarify how the terminology “failure” and “poor outcome” are used. This would facilitate comparisons across studies. Still, these terms are often treated as similar concepts in the literature.

Because most of the patients who get worse after microdiscectomy have a favourable ODI score at follow-up, and specific risk factors for deterioration are present, one could consider patients who got worse as a special clinical entity among the “failures”. At least they should be accounted for in outcome studies.

According to our data, duration of leg pain is probably not an independent risk factor for an unfavourable outcome when adjusting for the duration of sick leave. Future studies could clarify this issue.

Conclusions

Few patients get worse after microdiscectomy. Patients who have been unable to work for a longer period of time, despite a fairly good functional level, should be informed that they run a higher risk for deterioration. In prospective studies, the *change* in functional score should be reported, so that a more accurate failure rate can be assessed.

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Figure 1.
Study population.

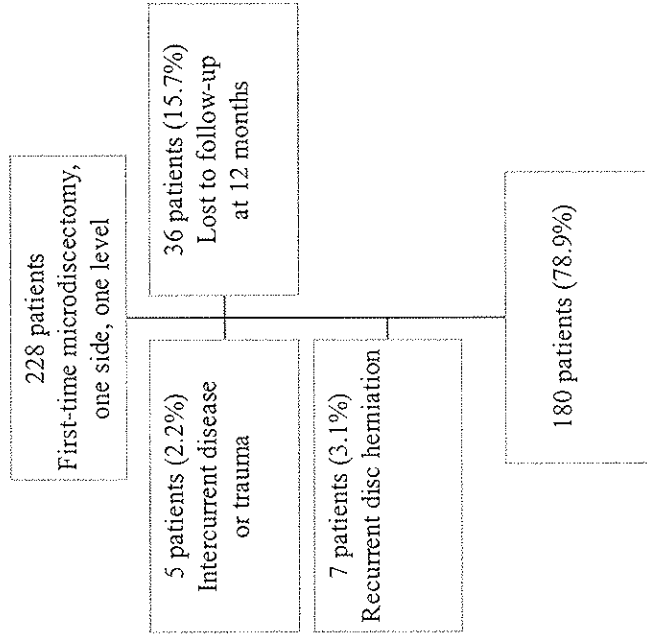


Table 1. Employment Status

	<u>Number of patients (%)</u>	
	Baseline N=180	12 months N=179 ^a
On sick leave	124 (69)	18 (10)
Working part time	11 (6)	6 (3)
Working full time	16 (10)	108 (61)
Homemaker, student, unemployed or retired pensioner	49 (9)	20 (12)
On rehabilitation ^b	9 (5)	21 (11)
Disabled pensioner	2 (1)	6 (3)

^a One missing value. ^b Patients who have received workers compensation more than 12 months with prospect of either returning back to work or permanent disability status.

Table 2. Overall effects of lumbar microdiscectomy, 180 cases.

	<u>Baseline</u>	<u>12 months follow up</u>	<u>Improvement</u>		
	Mean (SD, 95% CI)	Mean (SD, 95% CI)	Mean (SD, 95% CI)	P-value	Effect Size
ODI	49.5 (21.2, 46.4 – 52.6)	13.4 (13.0, 11.4 – 15.3)	36.2 (23.6, 32.7 – 39.6)	< 0.001	1.7
VAS Back pain	51.7 (29.3, 47.4 – 56.0)	21.3 (22.6, 18.0 – 24.6)	30.4 (35.6, 25.2 – 35.6)	< 0.001	1.0
VAS Leg pain	63.4 (27.5, 59.3 – 67.4)	16.8 (21.1, 13.7 – 20.0)	46.5 (33.4, 41.6 – 51.4)	< 0.001	1.7

Table 3 Characteristics of the seven patients who had an increase in ODI score 12 months after microdiscectomy

Gender (age)	ODI score at 12 months (change)	Percent deterioration of preoperative ODI score	Preoperative work status	Postoperative work status, 12 months	Back pain (Δ VAS)	Leg pain (Δ VAS)	Surgeons diagnosis at 12 months	Complications
M (47)	40 (8)	25	Working 50%	Sick-leave	Better (34)	Better (2)	Neuropathic leg pain	None
F (33)	40 (12)	42	Sick-leave	Working 50%	Better (11)	Better (25)	Unspecific back pain	None
M (39)	38 (4)	12	Working 25%	Working 30%	Better (16)	Better (33)	Unspecific back pain	None
M (51)	28 (4)	17	Working 75%	Working full time	Better (28)	Better (8)	Myofacial back pain	Superficial wound infection
M (44)	28 (16)	133	Sick-leave	Rehabilitation	Worse (2)	Worse (29)	Myofacial back pain	None
F (42)	48 (6)	14	Sick-leave	Sick-leave	Better (5)	Worse (5)	Neuropathic leg pain	None
M (56)	22 (4)	22	Sick-leave	Working full time	Worse (21)	Better (13)	Unspecific back pain	None

Table 4. Significance of deterioration in ODI score and multivariate analyses of risk factors.

Group (N)	I (173)		II (7)	Significance of mean differences between group I and II	Risk factor analyses.			
	<u>Not deteriorated</u> Improved (172) unchanged (1)		<u>Deteriorated</u>		Binary stepwise logistic regression			
Factors				P-value	β^a	P-value	β^b	P-value
Weeks of sick leave/rehabilitation Mean (SD)	17.7 (21.7)		60.4 (60.9)	> 0.001	0.032	0.001	0.058	0.010
Preoperative ODI score Mean (SD)	50.4 (21.1)		27.1 (10.1)	0.004	-0.087	0.011	-0.216	0.013
Duration of leg pain Mean (SD)	41.9 (63.4)		131.6 (179.9)	0.001	0.008	0.006	0.005	0.572
Duration of back pain Mean (SD)	87.8 (197.4)		191.0 (217.9)	0.178	0.001	0.304		
Preoperative VAS leg pain Mean (SD)	63.7 (27.7)		55.8 (22.5)	0.461	-0.009	0.481		
Preoperative VAS back pain Mean (SD)	51.6 (29.5)		54.4 (25.5)	0.804	0.003	0.800		
Age Mean (range)	40.1 (10.2)		44.6 (7.6)	0.387				

^a Age adjusted,

^b Adjusted for the two other factors (duration of sick leave/rehabilitation, preoperative ODI score or duration of leg pain) and BMI, gender, smoking, age and education.