Timing of surgery for sciatica

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CAN WE PREDICT SURGERY FOR SCIATICA?

Improving prediction of "inevitable" surgery during non-surgical treatment of sciatica.

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ABSTRACT

Background: After 6 weeks of sciatica surgery speeds up recovery. A randomized trial showed that conservative care yields results similar to early surgery at one year. However 39 % of this prolonged conservative care group ultimately underwent surgery during one-year follow-up. We evaluated variables to improve prediction of surgery in the conservatively treated cohort.

Methods: Baseline data on 142 patients enrolled in the conservative treatment arm of a randomized trial were analyzed to select those that could contribute to the prediction of surgery. The actual occurrence of surgery was used as the dependent outcome of interest. Variables measured at baseline included neurological examination results, the Visual Analogue score for pain (VAS) and the Roland Disability Questionnaire (RDQ).

Results: Of 142 patients receiving conservative care, 39 % underwent surgery after a mean period of 18.7 weeks. Higher pain intensity and higher functional limitations at baseline were associated with an increased likelihood of surgery during follow-up. Mutually adjusted Odds Ratios of 1.7 (95 % CI; 1.1 to 2.7) per 20 mm incremental intensification of pain on the VAS score and 1.8 (95 % CI; 1.2 to 2.9) per 3 points of deterioration of the RDQ score quantify the increasing chance of undergoing delayed surgery.

Conclusions: Despite maximal efforts to the contrary, surgery could not be prevented for a considerable proportion of patients in a conservatively treated cohort. Compared to those with lower pain and disability scores initially , patients with more intense leg pain or higher disability scores were at higher risk to undergo delayed surgery.

In general lumbar disk surgery for sciatica is performed to speed up recovery of leg pain and disability[161]. It ranks high among the most frequently performed surgical procedures for neuropathy and musculoskeletal disorders.[46;77]. The timing of surgery appears to vary greatly between different countries[46]. A recently published study revealed evidence that for the majority of patients both prolonged conservative care and early surgery resulted in complete recovery at one year but the conservative arm took twice as long to reach recovery[129]. Delayed surgery, however, had been necessary after all for 39 % of the patients assigned to the prolonged conservative treatment group, during the first year after randomization. Although the intention of prolonged conservative care reduced the number of surgical interventions substantially, those patients who underwent surgery at a later date suffered from pain and disability for quite a prolonged period, up to 6 months. It would be of great value to patients opting for a strategy of prolonged conservative care, if determinants available early in the course of sciatica could be found that would improve the prediction of surgery during follow-up. Therefore we evaluated the predictive value of clinical, demographic, and radiological variables for surgery actually performed in the conservative treatment cohort of a recently conducted randomized trial.

METHODS

A multicenter prospective randomized trial of patients with short-term severe sciatica was conducted to determine whether early surgery resulted in a more effective outcome during the first year compared to a strategy of prolonged conservative treatment (including, if indicated, delayed surgery). The medical ethics committee at each of the 9 participating hospitals approved the protocol. Written informed consent was obtained from all patients. Details of the design and study protocol were published previously[118;129].

Patients

Eligible patients were 18-65 years of age, with radiological confirmation of a clinically expected disk herniation causing an incapacitating lumbosacral radicular syndrome lasting between 6 and 12 weeks as documented by the attending neurologist. At the time of enrollment and randomization an independent research nurse verified persistence of complaints and the surgical indication. Cauda equina syndrome or severe paresis (MRC<3) were excluded as were identical complaints in the past twelve months, a history of spinal surgery, bony stenosis, spondylolisthesis, pregnancy or severe comorbidity.

For the purpose of the present analysis, the patients who originally were allocated at random to conservative care were selected as the study cohort.

Treatment

Prolonged conservative management was provided by the general practitioner. Ample information was provided about the favorable prognosis. If necessary the prescription of pain medication was adjusted according to existing clinical guidelines[44]. If there was considerable fear of movement, the help of a physiotherapist was recommended. Treatment was aimed mainly at resumption of daily activities. However if sciatica was still present at 6 months after randomization, microdiskectomy was considered if a repeat MRI still showed the disk herniation. Increasing drug-resistant leg pain or progressive neurological deficit were reasons for performing surgery even before 6 months. When patients requested surgery, they were again evaluated by their treating physician and the assigned research nurse, who had to confirm that recovery had not occurred and that the repeated MRI showed an unresolved disk herniation. Subsequently the neurosurgeon was consulted by the patient who requested surgery under the premise that further recovery was not to be expected in the next few months. If surgery was performed, the herniated part of the disk was removed together with as much degenerated nuclear material as possible [162]. Removal of bone to gain access to the disk space was minimized while total disk excision was never performed.

Variables

Prognostic determinants were selected on the basis of classical physiological hypotheses or inferred from earlier studies[2;163;164]. These socio-demographic, anamnestic, neurological, and radiological variables were collected before randomization was performed.

Outcomes

The occurrence of surgery performed during the course of prolonged conservative care was the event of interest. Functional outcome as indicated by means of the Roland Disability Questionnaire for Sciatica (RDQ)[114;165] and intensity of leg or back pain on a 100 mm visual analogue scale for leg pain (VAS-leg and VAS-back)[109] was assessed at 0, 2, 4, 8, 12, 26, 38 and 52 weeks, respectively. For the present analysis only data from the baseline measurements were used. Furthermore a 7-point Likert scale evaluated recovery. In a dichotomized form "satisfactory" outcome is similar to "complete" or "near-complete" recovery.

Statistical Analysis

Data collection and quality checks were performed using the ProMISe data management system of the Department of Medical Statistics & BioInformatics of the LUMC.

Table 1. Baseline scores and outcomes per treatment group at 12 months in patients initially started with a conservative treatment regimen *

	Conservative (n=87)	Late Surgery (n=55)	p-value
Roland baseline †	15.8±3.8	17.1±3.9	>0.05
12 months	3.9 ± 5.2	4.0 ± 6.2	>0.05
VAS leg pain base line (mm) ‡	64.0 ± 21.3	65.4 ± 21.3	>0.05
12 months	11.4 ± 17.5	13.4 ± 25.3	>0.05
VAS back pain baseline (mm) ‡	30.2 ±25.0	32.2 ± 32.3	>0.05
12 months	17.4 ± 21.3	14.6 ±24.8	
Satisfactory Recovery % §	79	85	>0.05 (Fisher's exact Test)

* Means and standard deviations
† The Roland Disability Questionnaire for Sciatica is a disease specific disability scale that measures functional status in patients with pain in the leg or back. Scores range from 0 to 23, with higher scores indicating worse functional status.
‡ The intensity of pain was indicated on a horizontal 100 mm visual analogue scale, with 0 representing no pain and 100 the worst pain ever experienced.
§ Likert global perceived recovery is defined by a 7-point scale "Worse" to "Complete" recovery. Satisfactory recovery is defined as complete or nearly complete recovery using the Likert 7-point scale.

All statistical analyses were carried out using SPSS, version 14.0[120]. All variables were recoded before being used in a logistic regression analysis as described previously in the protocol[118]. Since the VAS leg pain and RDQ are both continuous variables and the Odds Ratios of these variables correspond by definition to the effect of an increase in 1 unit of the underlying scale, these were rescaled (without any effect on their significance) for reporting purposes to let the Odds Ratios reflect the effect of an increment of 20 mm and 3 points respectively, both corresponding to the estimated Minimal Clinical Important Difference[166;167].

The predictive effect of variables was analyzed by constructing a multivariable logistic regression model with "the occurrence of surgery during the first twelve months" as the outcome of interest. The model was obtained using a stepwise backward elimination process with threshold values of 0.10 and 0.05 for removal and inclusion of predictors. Since follow-up observation was complete, there was no censoring and a survival modelling approach was not necessary, the outcome of interest simply being the probability of having undergone surgery by month 12 after being randomized to conservative care.

Finally, after having constructed the model that retained all significant predictors, the estimated probabilities were tabulated using some typical values of the predictors and the estimated odds ratios were tabulated with their respective confidence

Table 2. Uni- and multivariate analysis of baseline variables to determine predictive value on delayed surgery.

Variable	Comparison (%)	Univariate analysis			Multivariate analysis		
		OR	95 % CI	p value	OR	95% CI	p value
Gender	Female (32) vs Male (68)	0.80	0.37-1.70	0.56	-	-	-
Age (years)	≥ 40 (63) vs <40 (37)	1.04	0.51-2.13	0.92	-	-	
Job *	Mentally (69) vs Physical (31)	*0.56*	*0.29-1.09*	*0.09*			*0.89*
Housewife	Yes (10) vs No (90)	2.87	0.93-8.81	**0.066**	-	-	0.27
Spouse/partner	Yes (78) vs No (22)	1.38	0.58-3.28	0.47			
Children	Yes (68) vs No (32)	1.70	0.78-3.69	0.18			
Smoking	Yes (39) vs no (61)	1.00	0.49-2.04	0.99			
Quetelet index	Per 1 point increments	1.10	0.98-1.23	**0.093**	-	-	0.17
Start sciatica	Slowly (67) vs Acute (33)	1.66	0.80-3.43	0.17			-
Sciatica provoked by							
Sitting	Yes (75) vs No (25)	1.27	0.56-2.86	0.56			-
Coughing, sneeze	Yes (72) vs No (28)	1.13	0.52-2.46	0.75			-
Straight leg raising †	Pos. <60°(74) vs Neg. ≥ 60° (26)	1.52	0.66-3.49	0.32			
Crossed leg raising	Positive (57) vs Negative (43)	0.61	0.30-1.21	0.16			-
Kemp's sign	Positive (56) vs Negative (44)	2.75	1.31-5.79	**0.008**	2.18	0.85-5.36	0.09
Finger-ground in cm	>30 (59) vs ≤ 30 (41)	1.55	0.75-3.23	0.24			-
Bragard's test	Positive (28) vs Negative (72)	1.52	0.68-3.40	0.30			-
Sensory disturbance	Yes (91) vs No (9)	2.80	0.59-13.4	0.20			-
MRI-level herniation	L5S1 (66) vs L4L5 and L3L4 (34)	0.95	0.49-1.83	0.88			-
MRI-sequester	Yes (42) vs no (58)	0.84	0.43-1.63	0.61			-
Preference surgery	Mild (66) vs Strong (34)	0.48	0.23-0.98	**0.044**			0.72
Roland Disability (0-23)	Per 3 points increments	2.08	1.24-3.49	**0.006**	1.8	1.21-2.90	**0.007**
VAS leg pain (0-100mm) ‡	Per 20 mm increments	1.65	1.05-2.6	**0.030**	1.72	1.11-2.67	**0.015**
Roland difference (T2w-T0) §	Worse or equal (37) vs improved(63)	1.51	0.60-3.81	0.38			-
	Better	1.00	-		-	-	
	No difference or worse				-	-	
VAS difference (T2W-T0) ‡	Worse or equal (35) vs improved(65)	1.37	0.56-3.36	0.49			-

* Intellectual or physical jobs were defined by the patient.

† Lasègue's sign was defined positive if the examiner observed a typically dermatomal area of pain reproduction and pelvic muscle resistance during unilateral provocative straight leg raising below an angle of 60 degrees, and crossed positive if the same experience was noted raising the other leg below 90 degrees.

‡ The intensity of pain was indicated on a horizontal 100 mm visual analogue scale, with 0 representing no pain and 100 the worst pain ever experienced.

§ The Roland Disability Questionnaire for Sciatica is a disease specific disability scale that measures functional status in patients with pain in the leg or back. Scores range from 0 to 23, with higher scores indicating worse functional status.

Bold text defines statistical significance of variables in analysis.

Table 3. Classification table based on regression formula.

	Per protocol treatment	Predicted group membership (%)	
		Predicted non- surgical	Predicted surgery
Original †			
	Conservative	84.6	15.4
	Surgery	57.1	42.9
Cross-validated* ‡			
	Conservative	83.5	16.5
	Surgery	63.3	36.7

* Cross validation was done only for those cases in the analysis. In cross validation, each case is classified by the functions derived from all cases other than that case.
† 70 % of original grouped cases are correctly classified.

‡ 67 % of cross-validated grouped cases are correctly classified.

intervals. Whether prediction is actually possible in a reliable way for an individual patient can be seen in a classification table under the assumption of allocating the patient to "surgery" if the probability of surgery is more than 50 % (as is common in, for example, diagnostic tests). In view of the restricted size of the study population we focused solely on identifying significant risk factors for surgery. No attempts were made to perform a more refined analysis with an ROC curve or a training/validation subset approach. However we did a linear discriminant analysis (almost identical to a logistic regression model in this case) to obtain a classification table which is usually shown with a diagnostic test context with cross-validated percentages of correctly classified cases.

RESULTS

Of 142 patients assigned to receive prolonged conservative care, 55 (39 %) underwent surgery after a mean period of 18.7 (95 % CI 14.3 to 23.0) and median 14.6 (Interquartile range; 6.4 to 26.0) weeks. Before randomization the mean period of sciatic complaints was 9.5 (SD; 2.11) weeks for all patients treated conservatively initially. The mean Roland disability score for the 55 surgical patients was 15.0 (95 % CI; 13.3 to 16.8) shortly before surgery, while the mean visual analogue score at that time was 54 (95 % CI; 46.2 to 61.8) mm. Repeated surgery within the first year was performed in a single case. Mean baseline and one-year outcome scores for those eventually undergoing surgery in the conservative arm were not significantly different from the

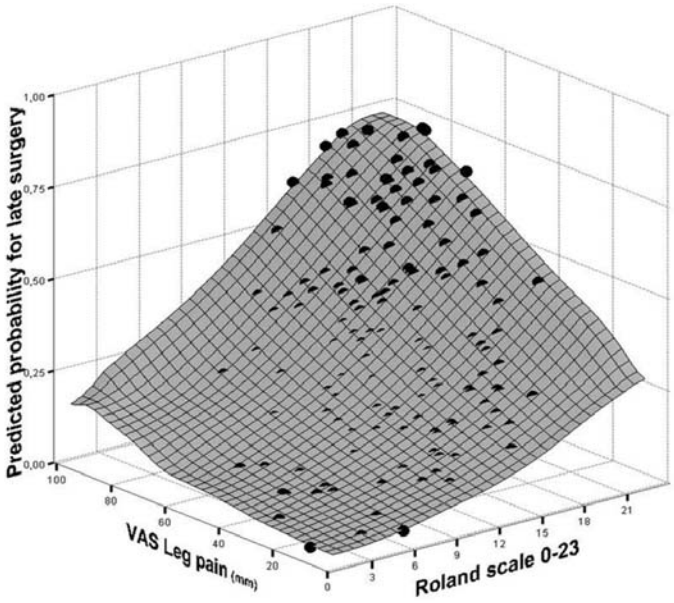

Figure 1: 3-D Scatter plot illustrating predicted probabilities of surgery as a function of VAS leg pain and RDQ at randomisation.*

** A patient with a Roland score of 20 and VAS leg pain of 79 mm has a predicted probability to undergo delayed surgery of 0,60, while for a patient with a Roland score of 8 and VAS leg pain of 61 presents a risk of 0.16.*

• Individual study patients.

scores for those treated without surgical intervention; the same holds for the proportion of recovered patients (Table 1).

Univariate logistic regression models with surgery as the event of interest did not reveal a significant association with the classical anamnestic, neurological and radiological variables (Table 2). Univariately significant odds ratios were obtained for "initially recorded leg pain intensity" (VAS; p=0.03), disability (RDQ; p=0.006) and the "Kemp neuroforamen compression test" (p=0.008), as well as for "magnitude of preference for surgery" (p=0.04). After entering these variables into one multivariable logistic regression model and performing a backward stepwise analysis, VAS leg pain intensity and severity of sciatica-specific disability RDQ were retained as significant factors. The adjusted Odds ratios were 1.7 (95 % CI; 1.1 to 2.7) per VAS 20 mm incremental increase in pain and 1.8 (95 % CI; 1.2 to 2.9) per 3 points deterioration on the RDQ score (Table 2).

Predictability of the risk to undergo delayed surgery seems high by the estimated odds ratios of leg pain intensity and disability, but the absolute risk never exceeds

levels higher than 80 % (table 3). Hence the sensitivity of the combined information of the two scores at intake and randomization is only around 43 % and the specificity is around 85 % with a total probability of correctly classifying surgery being estimated at 70 % (67 % cross-validated).

Since odds ratios describe relative effect sizes only, the estimated absolute risks of surgery as a function of combinations of pain and disability scores of the study patients is presented (Figure 1) to illustrate the estimated magnitude of the problem.

DISCUSSION

Delayed surgery did not lead to any differences in patient outcome at one year when compared to those treated strictly conservatively in a cohort of patients who had suffered from 6 to 12 weeks of sciatica. Baseline intensity of VAS leg-pain and RDQ disability scores were strong and independent determinants to predict delayed surgery, whereas traditional signs such as the straight leg raise test and the size or configuration of the disk herniation had similar distributions in the two groups.

High initial pain and disability scores were found to be predictive of a higher chance on delayed surgery in this study. However, these indicators are not yet used for the regular care of sciatica patients [114] but may be valuable in the decision process to opt for early surgery or for prolonged conservative care. Indeed, if initial scores after 6 to 12 weeks of persistent sciatica correspond to severe disability plus high pain intensity and do not regress after a few more weeks of 'wait-and-see', one may infer that the risk of surgery at a later stage is high. These patients might consider surgery without further delay to reduce the period of suffering and absence from work.

Previously we described the lack of interaction between initial pain intensities and the allocated timing of surgery on speed of recovery[129]. These analyses, however, were bound to an Intent-To-Treat methodology and the current 55 surgical patients were, thus, part of the prolonged conservative treatment arm as it was a pragmatic randomized controlled trial comparing two different timing-of-surgery strategies. The current analysis describes the predictive value of pain intensity for surgery performed at a later stage, instead of the possible interaction effects on speed of recovery or outcome per se.

The current results are clear but some restrictions in study design must be considered. Patients were recruited from neurological outpatient clinics after the usual referral by primary care physicians who stated that their patient had persistent sciatica and requested for surgery. One may concur that disability and pain are measured by subjective questionnaires which, except for study purposes, are not yet used for the

daily care of spine patients[167]. However, due to a lack of diagnostic, prognostic and outcome properties of neurological and radiological signs, these validated low back disease-specific questionnaires might be the best tools we have today to fulfil the request of society to measure quality of care.

So far, this is the first study that thoroughly analyzed variables which possibly affect the risk to undergo surgery in a conservative treatment regime for patients with 6 to 12 weeks of severe sciatica[47]. Although our findings may not be surprising for most physicians, we do not use these instruments for the regular care of sciatica patients. Obviously it is important to quantify the influence of pain and disability on the timing of surgery. Since timing of surgery did not influence outcome at 1 year the main indication for early surgery is to shorten the period of suffering. High pain intensities and disability scores complemented by personal preferences are valid arguments in support of the choice of surgery[168].

Despite maximal efforts of patients and physicians, surgery seems inevitable for a considerable proportion of a conservatively treated cohort. Compared to those with "tolerable" pain and disability, patients, who experience more intense leg pain and worse disability scores, run a higher risk of prolonged suffering and undergo delayed surgery and therefore might urge the spine surgeon to opt for earlier surgery to shorten their period of illness. Obviously we still can not reliably estimate exactly which patient will receive surgery during the follow-up period although the prediction is significantly improved when using these scales.