Factors Predicting Failure of Conservative Treatment in Lumbar-Disc Herniation

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Objective: *To explore factors predicting failure of conservative treatment in lumbar-disc herniation.*
Background: *Sciatica due to lumbar-disc herniation is a common complaint of spine patients. Even though the natural course is favorable, surgery is necessary in at least 10% of cases. Current trends show surgery to be more cost-effective than prolonged conservative care. However, there is limited information about the usefulness of clinical and radiographic parameters to classify patients who are likely to fail conservative treatment.*
Material and Method: *Medical records of patients diagnosed with lumbar-disc herniation between January 1, 2007 and December 31, 2009 were studied. The records of patients in conservative and surgery groups were compared, for clinical features, MRI results and treatment modalities.*
Results: *Fifty cases (discectomy) and 50 controls (successful conservative treatment) were enrolled. Demographic data, presenting symptoms and physical examination did not differ, apart from duration of symptoms. Logistic regression analysis did not find a significant association between percentage of canal compromised after controlling for disc-fragment size, duration of symptoms and types of disc herniation. However, disc fragment size was strongly associated with surgical outcome (OR = 2.6). Duration of symptoms (OR = 1.2) and sequestered type of lesion (OR = 12.3) were associated with surgery in this model. The use of physiotherapy and epidural steroid injections was lower, but the failure rate was higher.*
Conclusion: *Long-duration, sequestered herniation and large fragment are predictive of failure in the conservative treatment of lumbar-disc herniation.*

Keywords: *Lumbar-disc herniation, Disc-fragment size, Sequestered disc lesion*

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Sciatica is one of the most common complaints of patients seeking consultations about spinal problems. The condition is typically caused by lumbar-disc herniation. It is estimated that lumbar-disc herniation accounts for about 5% of lower back pain (LBP) and is the most common indication for back surgery[1-3]. The natural course of lumbar-disc herniation is usually favourable. Most patients can be treated successfully by conservative means and surgery is definitely indicated for those with major neurological impairments or progressive neurological deficits despite conservative treatment[4-6]. In real situations, most surgical cases are due to relative indications, *i.e.*, persistent pain refractory to conservative treatment and affecting quality of life[7,8]. For patients without neurological deficits, however, there is no consensus on how long conservative therapy should be tried before surgery is considered. One study investigated this aspect and found that duration of sciatica > 12 months was associated with a less favorable outcome[9]. A prospective study comparing surgery and conservative care showed that a high percentage of patients in the conservative group had to undergo surgery several months later[7]. Several studies compared early surgery and prolonged conservative care; their findings favored early surgery because of faster recovery time and early return to work. Some cost-effectiveness studies[10-13] showed that surgery for lumbar-disc herniation was cost-effective over various follow-up periods. However, care should be taken to balance early surgery, which may put patients at unnecessary risk, and prolonged

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conservative care, which may involve extended suffering. The literature review revealed no study that systematically investigated how to classify patient likelihood to fail conservative treatment. Some studies tried to demonstrate the prognostic value of consecutive factors for the outcomes of both conservative and surgical treatments[14-17]. For example, Carragee et al[16], in a prospective study of 188 patients with sciatica in 1997, investigated the correlation of Magnetic Resonance Imaging (MRI) findings (disc fragment and canal morphology) and outcomes of treatment. They concluded that demographic and clinical features appeared to predict the outcomes of non-operative treatment, whereas disc-herniation and spinal-canal morphometric features seen on MRI were much more powerful predictors of surgical outcomes. They found significant differences between conservative and surgical groups for maximum AP disc diameter. Carlisle et al[17], in a retrospective case-control study (44 cases versus 44 controls) in 2005, investigated the value of quantitative MRI measurements in assisting decision-making for surgery or non-operative management. Their findings showed a trend for patients treated with surgery to have larger disc herniation areas and smaller canal cross-section areas, corresponding to larger percentage canal compromise, than the non-operative group. Nevertheless, neither study systematically showed whether, using information from routine clinical practice, it was possible to differentiate between those who would likely succeed with conservative treatment from those who would likely fail and need surgery. Thus, the aim of the present study was to investigate consecutive factors in routine clinical practice, to compare groups of patients who failed conservative treatment and had to undergo early surgery to shorten the duration of suffering, with those who underwent conservative treatment.

Material and Method

Study design

The present case-control study utilized the medical records of patients diagnosed with lumbar-disc herniation at Bumrungrad International Hospital, Bangkok, between January 1, 2007 and December 31, 2009.

Study population

One hundred medical records of patients (50 cases and 50 controls) diagnosed with lumbar-disc herniation at Bumrungrad International Hospital and who met the inclusion criteria, were identified from the Medical Record Department using the hospital's Microsoft® Amalga Health Information System (HIS) 2009 (http://www.microsoft.com/amalga/products/microsoftamalgahis/default.mspx). The present study population comprised patients who were aged 18 to 60 years, had single-level lumbar-disc herniation at the level and side corresponding to clinical symptoms, had radicular pain (below the knee for lower lumbar herniation and into the anterior thigh for upper lumbar herniation) and had evidence of nerve-root irritation with a positive nerve-root-tension sign or a corresponding neurological deficit. Those with a history of prior back surgery, other associated lumbar-spine pathology, or more than one level of disc herniation, were excluded. The authors also excluded patients who were operated on due to neurological deficits, retaining only patients who were operated on due to persisting pain and refractory to conservative treatment. Bumrungrad International Institutional Review Board (BI/IRB) provided scientific and ethical review and approved the present study.

Case definition (surgical case)

Medical records of patients diagnosed with lumbar-disc herniation that underwent a surgical discectomy (one level) due to persistent pain refractory to at least six weeks of conservative treatment.

Control definition (conservative treatment)

Medical records of patients diagnosed with lumbar-disc herniation who were successfully treated with conservative treatment with at least six months follow up period without significant recurrent pain.

The hospital records of both case and control patient groups were accessed and matched within $\pm$ 1 month to ensure the same treatment philosophy, the same technology and the same treatment modality that the patients would have received at that time.

Study variables

Patient data were extracted from the hospital records, *i.e.*, age, sex, body mass index (BMI), smoking history, co-morbidity, history of back pain, sciatica, numbness, duration of symptoms (from onset of disease to first consultation at study hospital), failure of injection therapy and failure of physiotherapy. Physical signs collected included nerve-tension signs, sensory impairment, motor weakness and functional

scoliosis. Imaging studies were also collected, *i.e.*, size of disc herniation, type of disc herniation, position of disc herniation, maximum AP diameter of disc fragment, and percentage of canal compromised.

Sample size

The authors assumed $\alpha = 0.05$ (2-sided test), and the baseline antero-posterior (AP) disc diameter among controls as 4.7 ± 1.9 millimeters, compared with 6.8 ± 2.8 millimeters for clinical significance[16] the statistical power (1-β) of the present study was $\geq 99.8\%$ with a sample size of 50 cases and 50 controls.

Statistical analysis

Means were compared with the Student's t-test and analysis of variance (ANOVA), where applicable, while Chi-square (χ^2) tests were used to compare proportions and odds ratios (OR) to measure strength of association. For multivariable analysis, backward step-wise unconditional logistic regression was used to determine strength of association, adjusting for potential confounders and to assess possible interactions. Statistical significance was set at $\alpha = 0.05$ (2-sided test). Stata 9.2 SE (StataCorp, College Station, TX, USA) was used for data analysis.

Results

Patient characteristics

Fifty cases (discectomy) and 50 controls (successful conservative treatment) that were eligible according to the inclusion criteria, were enrolled between January 1, 2007 and December 31, 2009. Most

Table 1. Cases and controls demographic characteristics, reported symptoms and signs

Parameters	Total	Case	Control	Odds ratio	95% confidence interval or p-value
Sex					
Female	35	14	21	1.0*	0.8-4.3
Male	65	36	29	1.9	
Age (mean $\pm$ SD, years)	43.7 (10.0)	45.3 (10.4)	42.1 (9.3)		p = 0.11
BMI (mean $\pm$ SD, kg/m^2)	24.7 (4.0)	24.7 (4.1)	24.7 (4.0)		p = 0.96
Occupation					
Business	32	12	20	1.0*	
Office worker	33	19	14	2.3	0.8-6.1
Others	35	19	16	2.0	0.7-5.3
Smoking					
No	94	46	48	1.0*	
Yes	6	4	2	2.1	0.4-11.9
Medical co-morbidity					
No	93	45	48	1.0*	
Yes	7	5	2	2.7	0.5-11.4
Duration of symptoms** (mean $\pm$ SD, weeks)	13.8 (17.2)	22.7 (20.0)	4.9 (5.9)		p < 0.001
Presenting symptoms					
Back pain	1	0	1	1.0*	p = 0.37
Buttock and leg pain	98	49	49	Not calculable	
Buttock, leg pain and weakness	1	1	0	Not calculable	
Functional scoliosis					
No	83	37	46	1.0	
Yes	17	13	4	4.0	1.2-13.4
Neurological signs					
Normal	16	7	9	1.0	
SLRT positive	42	12	22	0.7	0.2-2.4
SLRT positive & others	34	26	16	2.1	0.6-6.7
Sensory impairment and weakness	8	5	3	2.1	0.4-12.2

* Reference

** Time from onset of symptoms to the first consultation at study hospital

SLRT = straight leg raising test

of the present study samples were males (65%), with a mean age (± SD) of 43.7 ± 10 years and a normal body mass index (BMI), who had experienced symptoms on average for 13.8 ± 17.2 weeks. Fewer than 10% were smokers or had co-morbidities and about one-third each were business people, office workers and other occupations. Nearly all (98%) presented with buttock and leg pain. Seventeen percent had functional scoliosis, 42% were straight-leg-raising-test (SLRT)-positive, 34% were SLRT-positive with other findings, and 8% had some neurological deficit (Table 1).

Table 1 shows the bivariable analysis of cases and controls. The two groups were not statistically significantly different with regard to age, sex, BMI, occupation, smoking status, presence of co-morbidity, presenting symptoms, or presence of neurological signs ($p > 0.05$ for any variables). The cases, however, had about 17 weeks' longer duration of symptoms ($p < 0.05$).

The findings from the patients' MRI scans are shown in Table 2. Nearly half the herniation occurred at the L4-5 level (49%), followed by the L5-S1 level (35%). Forty-four percent were of the extruded type, followed by protruded (30%) and sequestered (26%) types. Most cases (74%) had paracentral herniation. The mean disc-fragment size (± SD) was 8.7 (± 1.7) millimeters for the cases and 5.3 (± 1.8) millimeters for the controls, with mean percentage spinal canal compromised values (± SD) of 51.7 (± 10.6) millimeters and 35.1 (± 11.2) millimeters, respectively, all of which were statistically significantly different ($p < 0.05$). The differences in level of herniation between cases and controls were not statistically significant, but the cases were more likely to have sequestered lesions than the controls, and the controls had more protruded-type lesions than the cases. Furthermore, the cases' lesions were about 3 millimeters larger, with 16% more of the spinal canal compromised than the controls ($p < 0.05$). In addition, the authors investigated two treatment modalities usually offered to patients with lumbar-disc herniation-physiotherapy and epidural steroid injection (Table 3). There appeared to be lower utilization rates for both physiotherapy and epidural steroid injection among the cases than the controls (34/50 vs. 50/50, and 11/50 vs. 27/50, respectively). The failure rate (no relief) was higher among the cases for both treatment modalities (15/34 vs. 1/50, and 6/11 vs. 0/27). It is unfortunate that odds ratios were not calculable, because of zero frequencies in some cells. Using logistic regression, no significant association was found between percentage of canal compromised after controlling for disc-fragment size, duration of symptoms, and type of disc herniation. Disc-fragment size, however, was strongly associated with a surgical outcome (OR = 2.6). Duration of symptoms (OR = 1.2) and sequestered-type lesion (OR = 12.3) were also

Table 2. Comparison of magnetic resonance imaging (MRI) findings between cases and controls

Parameters	Total	Case	Control	Odds ratio	95% confidence interval or p-value
Spinal level of disc herniation					
L1-2	2	1	1	1.0*	
L2-3	3	1	2	0.5	0.1-19.6
L3-4	11	4	7	0.6	0.3-11.8
L4-5	49	27	22	1.2	0.7-20.7
L5-S1	35	17	18	0.9	0.5-16.3
Type of disc herniation					
Extruded	44	27	17	1.0*	
Protruded	30	2	28	0.04	0.01-0.2
Sequestered	26	21	5	2.6	0.8-8.3
Position of disc herniation					
Central	20	8	12	1.0*	
Para-central	74	39	35	1.7	0.6-4.6
Foraminal	6	3	3	1.5	0.2-9.4
Mean (± SD) AP diameter of disc fragment (mm)	7.0 (2.4)	8.7 (1.7)	5.3 (1.8)		$p < 0.001$
Mean percentage (± SD) of spinal canal compromised	43.4 (13.7)	51.7 (10.6)	35.1 (11.2)		$p < 0.001$

* Reference

Table 3. Comparison of treatment modalities for cases and controls

Treatment modalities	Total	Case	Control	p-value*
Physiotherapy				
Relief	37	0	37	<0.001
Partial relief	31	19	12	
No relief	16	15	1	
Not applicable	16	16	0	
Epidural steroid injection				
Relief	26	0	26	<0.001
Partial relief	6	5	1	
No relief	6	6	0	
Not applicable	62	39	23	

* Odds ratio is not calculable due to zero frequencies in some cells

Table 4. Logistic regression analysis showing association between percentages of vertebral canal compromised with the cases and controls status*

Variables	Odds ratio	95% confidence interval
Canal compromised (%)	1.1	0.90-1.2
Disc-fragment size (mm)	2.6	1.20-6.1
Duration of symptom (wk)	1.4	1.10-1.7
Type of disc herniation		
Extruded	1	
Protruded	0.2	0.01-4.1
Sequestered	12.3	21.50-101.1

* Hosmer and Lemeshow goodness-of-fit test for the model, $p > 0.99$

associated with a surgical outcome in the present model (Table 4).

Discussion

The presented data showed that disc-fragment size, measured by the AP diameter of the herniated part, was strongly associated with surgery. This finding was similar to that of Caragee et al[16]. This may demonstrate the significance of the magnitude of mechanical compression of the disc fragment on the nerve root, which may play an important role in decision-making. Another parameter consistent with this trend was duration of symptoms, where the non-operative group had shorter duration than the surgery group. A possible explanation is that the authors body may have the ability to cope with nerve-root compression from disc herniation for a limited time, but that persistent symptoms may reduce the likelihood for the problem to be self-limiting. The study by Caragee et al[16] found where the duration of symptoms in the current episode was short; this was associated with a good outcome using non-operative care, but a good surgical outcome needed < 6 months of symptoms.

The sequestered type of disc herniation did yield a surprising finding; this type of disc herniation was associated with surgery, which did not agree with the findings of Saal et al[4]. The study by Komori et al[5] showed that disappearance of the herniated nucleus palposus was frequently seen in migrating-disc herniation, and corresponded with clinical outcome; they presumed that exposure to vascular supply had a major role in this phenomenon. The authors, however, hypothesized that patients with sequestered-disc herniation experienced chemical irritation of the nerve root, due to direct exposure of the nucleus palposus, together with mechanical compression, resulting more likely in surgery.

Another interesting finding from the present study was the utilization rate of epidural steroid injection and physiotherapy, which was lower in the surgery group than the non-operative group. It seems that increased utility rates of these two treatment modalities may increase success rates for non-operative treatments in patients with lumbar-disc herniation. However, the presented data demonstrated higher failure rates for both modalities in the surgery group. The authors recommend that all non-operative treatment modalities be tried first; if the patient responds poorly, surgery may then be necessary.

The present study had some limitations. This was a case-control study with retrospective medical record review, so that there may have been selection bias due to non-randomization of the study population, even though bivariable analysis of cases and controls showed no statistical differences in demographic data or in most clinical presentations. The present study samples were attended by several surgeons, which could result in different treatment preferences and thresholds of surgical recommendation, as shown with the utilization rates for epidural steroid injection and intensive physiotherapy. It is also unfortunate that the odds ratios of these two treatment modalities were not calculable, because of zero frequencies in some cells. Sequestrated disc herniation theoretically do well with conservative treatment but the present study found a higher proportion of patients in the

surgery group having this type of herniation more than in the controls. The authors hypothesized that sequestrated disc causes both chemical irritation (inflammation) and mechanical compression to nerve root which lead to higher surgical demand of patients. Finally, duration of symptoms in the present study might not reflect duration of treatment, the present study variable that was not included in the present study.

The findings from the present study imply that all patients with lumbar-disc herniation, but without associated pathology and significant neurological deficits, should be treated initially using non-operative means with all modalities, including epidural steroid injection and intensive physiotherapy. However, the subgroup of patients who presented with long-standing symptoms (> 22 weeks), sequestered-type herniation, and large disc herniation size (> 8.7 mm AP diameter), should undergo early surgical decompression, if initial non-operative treatment fails to yield satisfactory results.

Further prospective randomized controlled trials, intended systematically to investigate all these clinical and radiographic parameters, including non-operative treatment modalities, are needed to classify patient subgroups more accurately, and to serve more-demanding patients satisfactorily.

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Potential conflicts of interest

None.

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ปัจจัยทำนายความล้มเหลวในการรักษาโรคหมอนรองกระดูกทับเส้นประสาทแบบอนุรักษ์

ชัยยุทธ สุธีรยงประเสริฐ, สมโภชน์ ไพบูลย์ศิริจิต, วีระพันธ์ ควรทรงธรรม, สุรพงษ์ อนุรักษ์เลขา, นันทเดช หิรัณยัษฐิติ, สำเริง เนติ

วัตถุประสงค์: *เพื่อค้นหาปัจจัยที่จะทำนายความล้มเหลวในการรักษาโรคหมอนรองกระดูกทับเส้นประสาทแบบอนุรักษ์*
วัตถุและวิธีการ: *ใช้การศึกษาแบบ case control จากเวชระเบียนของผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นโรคหมอนรองกระดูกทับเส้นประสาท ในช่วงวันที่ 1 มกราคม พ.ศ. 2550 ถึง 30 ธันวาคม พ.ศ. 2552 ทำการทบทวนเวชระเบียนของผู้ป่วยที่รักษาแบบอนุรักษ์ได้ผลดี (control) กับ ผู้ป่วยที่ได้รับการผ่าตัด discectomy เนื่องจากประสบความล้มเหลวจากการรักษาแบบอนุรักษ์ (case) โดยเปรียบเทียบข้อมูลทางคลินิก ผลการตรวจ Magnetic Resonance Imaging (MRI) การทำกายภาพบำบัด และการฉีดยาสเตียรอยด์เข้าโพรงกระดูกสันหลัง (Epidural steroid injection)*
ผลการศึกษา: *จากผู้ป่วยที่ได้รับการผ่าตัด discectomy 50 ราย เปรียบเทียบกับผู้ป่วยที่ประสบความสำเร็จในการรักษาแบบอนุรักษ์ 50 ราย ไม่พบความแตกต่างในข้อมูลประชากรศาสตร์ อาการนำและผลการตรวจร่างกาย ยกเว้นเพียงระยะเวลาที่มีอาการก่อนมารับการรักษา (Odds ratio [OR] = 1.2) นอกจากนี้พบว่า disc fragment size มีความสัมพันธ์อย่างสูงกับการได้รับการผ่าตัด (OR = 2.6) และ sequestered type ของรอยโรค (OR = 12.3) ยังมีความสัมพันธ์กับการได้รับการผ่าตัด การทำกายภาพบำบัดและการฉีดยาสเตียรอยด์เข้าโพรงกระดูกสันหลังพบมีการทำมากกว่าในกลุ่มที่ประสบผลสำเร็จโดยวิธีอนุรักษ์*
สรุป: *ระยะเวลาการป่วยที่นาน การมี sequestered herniation และการมี fragment ที่ใหญ่เป็นปัจจัยทำนายความล้มเหลวในการรักษาโรคหมอนรองกระดูกทับเส้นประสาทแบบอนุรักษ์*