Master's Thesis of Orthopedics

# Prediction of probability for performing surgical treatment in the patients with lumbar spinal stenosis according to the severity of stenotic lesions: a 5- to 10-year follow-up study

## 요추 척추관 협착증 환자에서 협착 병변의 중증도에 따른 수술적 치료 시행 가능성 예측: 5~10년 추적 연구

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# Prediction of probability for performing surgical treatment in the patients with lumbar spinal stenosis according to the severity of stenotic lesions: a 5- to 10-year follow-up study

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# Abstract

Background: We aimed to clarify difference in the surgical probabilities of lumbar spinal stenosis (LSS) with respect to surgical treatment according to severity of stenosis on magnetic resonance imaging (MRI) using qualitative grading system.

Methods: With the design of retrospective observational study, a total of 1,008 patients diagnosed with LSS between 2011 and 2014 at our hospital were followed up for the mean duration of 7.6 years (5.17-9.8 years). We investigated severity of central and foraminal stenosis on initial MRI using Lee classification system and whether surgical treatment was performed. Logistic regression models were used to identify risk factors for surgery.

Results: During the mean follow-up period of 7.6 years, grade 3 maximal central stenosis showed the highest percentage of surgical treatment (57.9%-62.3%) with no significant difference in surgical probabilities according to concomitant foraminal stenosis. Surgical probabilities in grade 2 maximal foraminal stenosis was 22.2%-62.3% depending on concomitant central stenosis. Surgical probabilities in grade 3 maximal foraminal stenosis, were 22.2%-62.3% and 33.3%-57.9%, depending on concomitant central stenosis. Maximal central stenosis of grade 3 (OR [95% CI]: 3.90 [2.75–5.54]) and maximal foraminal stenosis of grade 2 or 3 (OR [95% CI]: 1.59 [1.21–2.09]) were significant risk factors for surgical treatment.

Conclusions: The high grades of maximal central and foraminal stenosis were risk factors for surgical treatment. Surgical probabilities were increased with higher grade of central and foraminal stenosis during the mean follow-up period of 7.6 years.

These results imply that the natural history of LSS differs according to grade of maximal central and foraminal stenosis.

Keyword : lumbar spinal stenosis; natural history; surgical decision; magnetic resonance imaging; qualitative grading
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# Chapter 1. Introduction

Lumbar spinal stenosis (LSS) is the most common disease associated with back pain and walking disability in elderly patients [1, 2]. Previous studies have shown that LSS has a benign clinical course, and conservative treatment including analgesics and steroid injections for symptomatic relief should be considered before surgery [3, 4]. If back pain and walking disability exhibit no improvement despite conservative treatment, surgery is the reasonable option [3]. Surgical decisions are based on clinical symptoms, physical disability, and magnetic resonance imaging (MRI) findings [4–8].

While some studies have reported that the severity of stenosis on MRI does not correspond to the severity of symptoms and has no predictive value for the natural history of LSS [3, 4], other studies have reported that the severity of stenosis is correlated with deterioration of the clinical course [9, 10]. Wessberg et al. observed that patients with dural sac area (DSA) ≥0.5 cm2 showed spontaneous improvement in the visual analog scale (VAS) score, but those with DSA <0.5 cm2 did not [9]. Herno et al. reported that patients with block stenosis at myelography eventually required surgical decompression [10]. Therefore, consensus is still lacking regarding the probability of surgical decompression according to the severity of stenosis on MRI at diagnosis.

Despite the benign natural history of LSS [4], results of deterioration have been reported in some studies [3, 11]. Due to this uncertainty in the natural history and clinical course, some patients with LSS might continue with ineffective conservative treatment or undergo unnecessary surgery. Therefore, we hypothesized that there would be a difference in the probability of surgical decompression according to the grade of stenosis on MRI. This study aimed difference in the surgical probabilities of lumbar spinal stenosis (LSS) with respect to surgical treatment according to severity of stenosis on magnetic resonance imaging (MRI) using qualitative grading system.

# Chapter 2. Methods

## 2.1. Study design and population

The study was reviewed and approved by the institutional review board of the hospital. This retrospective observational study analyzed the data of patients with LSS through their electronic medical records (EMRs), picture archiving and communication system (PACS) and telephone interview.

Adult patients diagnosed with LSS between 2011 and 2014 at our hospital were included in the study. The diagnosis of LSS was based on radiological evidence of stenotic lesions on lumbar MRI, with corresponding symptoms such as pain, numbness, neurological deficits in the legs and buttocks, neurological claudication bladder and bowel dysfunction [12]. Exclusion criteria were death due to life-threatening disease, symptomatic Meyerding grade 3 or higher spondylolisthesis, congenital stenosis, previous spine surgery before initial MRI, spine surgery after initial MRI due to other diseases including herniated intervertebral disc, scoliosis, vertebral fracture and malignancy. Patients who did not respond to the telephone interview were also excluded.

All LSS patients were treated surgically under informed consent or preference-based shared decision-making process after sufficient conservative treatment. Surgical treatment was decided in cases with failure of conservative treatment or ongoing neurologic impairment. The EMRs and telephone interviews were reviewed to check whether surgery including posterior decompression, foraminotomy, or fusion surgery was performed for the treatment of LSS, as well as the timing of the operation during a follow-up period of 5.2-9.8 years until December 31th 2020. The period from the time of diagnosis to the time of telephone interview was defined as the follow-up period. Altogether, 1,537 patients with LSS who underwent MRI were reviewed. After exclusion, 1,008 patients were finally included, with a mean follow-up duration of 7.6 years (Fig. 1).

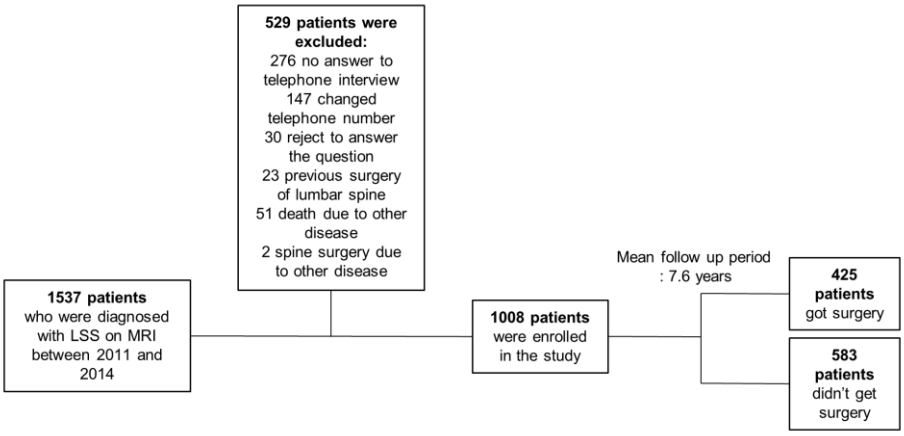


Figure 1. Flowchart of subject recruitment. LSS, lumbar spinal stenosis; MRI, magnetic resonance imaging

## 2.2. Diagnostic imaging

All patients with LSS underwent MRI examination. All images were obtained through electronic access to PACS, which is made up of Digital Imaging and Communications in Medicine format. All axial and sagittal T1, T2-weighted images of the lumbar spine were reviewed by the radiology department. The severity of central and foraminal stenotic lesions was qualitatively graded using T1, T2-weighted axial images at five available disc levels (L1-S1). We grouped LSS patients according to the severity of stenotic lesions using the Lee classification system to grade the severity of central and foraminal stenotic lesions, which showed excellent inter-reader and intra-reader reliability (Table 1) [13-15]. The narrowest lesions in the central canal and neural foramen which could explain the patients' symptoms on the initial electric medical records were defined as the maximal central and maximal foraminal stenosis, respectively. We also investigated the number of stenotic levels; thus, the number of disc levels with qualitative grading of the stenotic lesion was not zero.

Table 1. The qualitative grading systems of lumbar spinal stenosis on MRI.

| | Grade 0 | Grade 1 | Grade 2 | Grade 3 |
|---|---|---|---|---|
| Central lesion (Lee at al.;2011) | No stenosis | Mild stenosis with clear separation of each cauda equine | Moderate stenosis with some cauda equina aggregation | Severe stenosis with the entire cauda equina as a bundle |
| Foraminal lesion (Lee et al.;2010) | Normal | Perineural fat obliteration in the two opposing directions | Perineural fat obliteration in the four directions | Nerve root collapse or morphologic change |

## 2.3. Statistical analysis

Differences in continuous data between the groups were assessed using t test and analysis of variance. Differences in categorical data were assessed using the chi-squared test and linear-by-linear association. The risk factors for surgery were examined using a logistic regression model. Variables significantly associated with surgical treatment ($p < 0.20$) in the univariate logistic regression analysis were entered into the multivariate logistic regression model, which was used to calculate the odds ratios (OR) and 95% confidence interval (CI) of variables to predict surgical treatment using the backward elimination method. Survival data were analyzed using Kaplan-Meier survival curves and log-rank tests. IBM SPSS statistics version 19.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis.

# Chapter 3. Results

Among the 1,008 patients with LSS with a mean follow−up duration ± standard deviation (SD) of 7.6 ± 1.1 years, 425 (42.2%) patients underwent surgery. The mean age ± SD of the surgical group was 75.7 ± 10.3 years, which was significantly higher than that of the nonsurgical group (mean age ± SD, 74.0 ± 13.0 years) ($p = 0.019$). No significant difference was observed in the sex ratio between the groups ($p = 0.634$).

In case of central lesions, the proportion of patients who underwent surgery significantly higher in grade 3 of maximal central stenosis than the others ($p < 0.001$), but no significant difference was observed between grades 0, 1 and 2 of maximal central stenosis (Figure 2). In case of foraminal lesions, the proportion of patients who underwent surgery significantly lower in grade 1 of maximal foraminal stenosis than the others ($p < 0.05$) but no significant difference was observed between grades 0, 2 and 3 (Figure 3).

Surgical probabilities in grade 1, 2 maximal central stenosis were 22.5%–45.0%, 22.2%–41.7%, respectively, according to concomitant grades of maximal foraminal stenosis (Table 2). Grade 3 maximal central stenosis showed the highest percentage of surgical treatment (57.9%–62.3%) with no significant difference in surgical probabilities according to concomitant grades of maximal foraminal stenosis. When there is no concomitant central stenosis (grade 0 maximal central stenosis), the percentage of surgical patients of grade 2 and 3 maximal foraminal stenosis (44.3% and 46.8%, respectively) was significantly higher than that of grade 1 maximal foraminal stenosis (11.4%) ($p < 0.001$). The percentage of surgical patients increases significantly from grade 0 to grade 3 concomitant maximal central stenosis in grade 0 (22.5%–61.0%) and 1 (11.4%–59.1%) of maximal foraminal stenosis. Surgical probabilities in grade 2 and 3 maximal foraminal stenosis, were 22.2%–62.3% and 33.3%–57.9%, respectively, according to the grades of concomitant maximal central stenosis.

In a logistic regression, grade 3 maximal central stenosis (OR [95% CI]: 3.90 [2.75–5.54]) and grade 2 or 3 maximal foraminal stenosis (OR [95% CI]: 1.59 [1.21–2.09]) were significant risk factors for surgical treatment, but other variables including age, sex, and the number of central and foraminal stenotic levels were not significant (Table 3).

Kaplan–Meier curves and log−rank analyses showed significantly different rates of surgical treatment according to the grades of maximal central and foraminal stenosis (Figure 4, 5, 6). The survival curves showed plateau after initial steep drop for each grade, but survival rate did not actually converge to a constant value and decreases over time (Fig. 4). The slope of the plateau part of the survival curve is similar among each grade of stenosis

(Fig. 5, 6).

In case of maximal central stenosis, significant difference was observed in the survival curve between grades 3 maximal central stenosis and the others ($p < 0.001$)(Figure 5A). No significant difference was observed in the survival curve among grades 0, 1 and 2 of maximal central stenosis ($p = 0.337$). If there was no concomitant foraminal stenosis, significant difference was also observed in the survival curve between grades 3 maximal central stenosis and the others ($p < 0.001$)(Figure 5B). No significant difference was observed in the survival curve between grades 1 and 2 maximal central stenosis ($p = 0.248$).

In case of maximal foraminal stenosis, significant difference was observed in the survival curve between grades 1 maximal foraminal stenosis and the others ($p = 0.001$)(Figure 6A). No significant difference was observed in the survival curve between grades 0, 2 and 3 maximal foraminal stenosis ($p = 0.301$). If there was no concomitant central stenosis, significant difference was also observed in the survival curve between grades 2 or 3 maximal foraminal stenosis and the others ($p < 0.001$)(Figure 6B). No significant difference was observed in the survival curve between grades 2 and 3 maximal foraminal stenosis ($p = 0.779$).

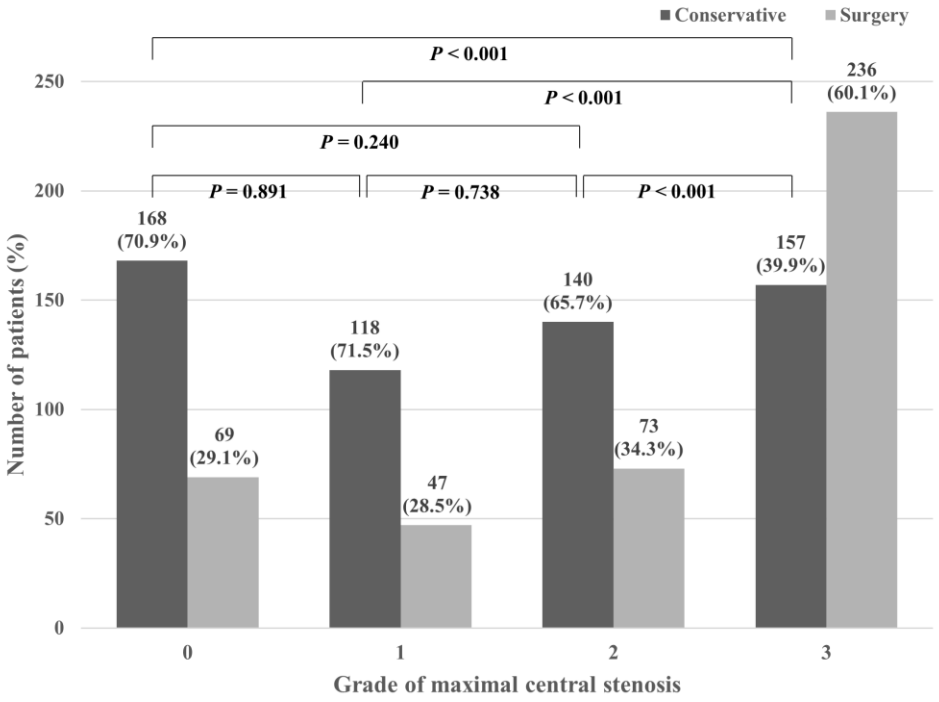


Figure 2. The number of surgical and conservative patients according to the grade of maximal central stenosis on MRI.

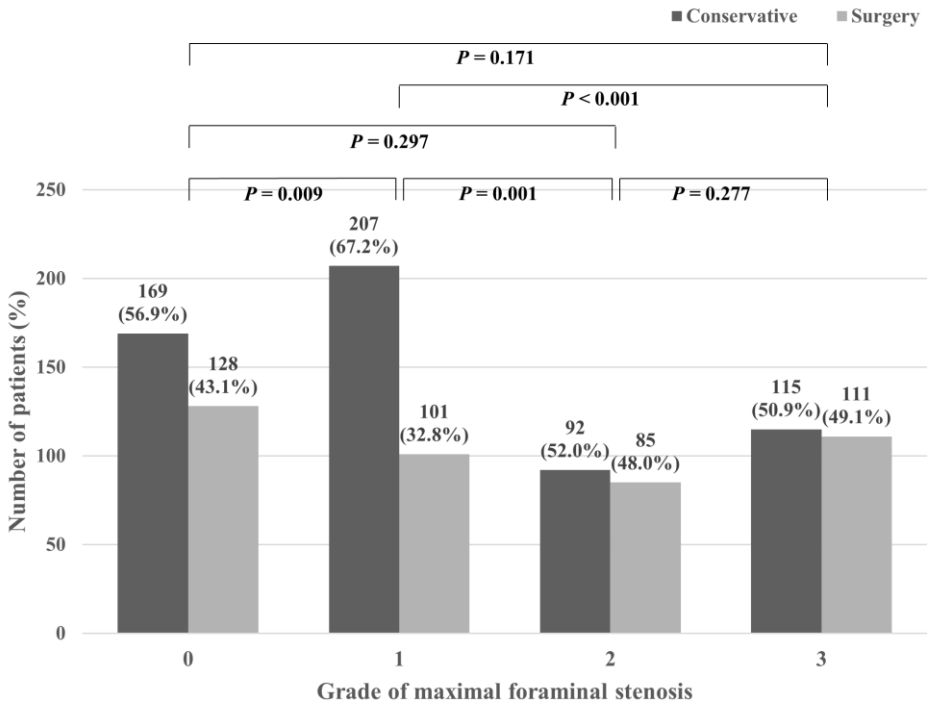


Figure 3. The number of surgical and conservative patients according to the grade of maximal foraminal stenosis on MRI.

Table 2. Percentage of surgical patients according to combination of grades of maximal central and foraminal stenosis.

| | | Grade of maximal central stenosis | | | | *P* value[a] |
|---|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 3 | |
| Grade of maximal foraminal stenosis | 0 | | 22.5% (16/71) | 30.6% (26/85) | 61.0% (86/141) | <0.001 |
| | 1 | 11.4% (13/114) | 28.3% (15/53) | 39.6% (21/53) | 59.1% (52/88) | <0.001 |
| | 2 | 44.3% (27/61) | 45.0% (9/20) | 22.2% (6/27) | 62.3% (43/69) | 0.084 |
| | 3 | 46.8% (29/62) | 33.3% (7/21) | 41.7% (20/48) | 57.9% (55/95) | 0.122 |
| *P* value[a] | | <0.001 | 0.110 | 0.395 | 0.738 | |

[a] linear-by-linear association test was used

Table 3. Univariate and multivariate logistic regression analyses of risk factors of surgical treatment.

| | Univariate analysis | | Multivariate analysis | |
|---|---|---|---|---|
| | Odds ratio (95% CI) | *P* value | Odds ratio (95% CI) | *P* value |
| Age (years) | 1.01(1.00–1.02) | **0.024** | | 0.914 |
| Sex (male) | 1.07 (0.82–1.39) | 0.634 | | |
| Maximum grade of central stenosis | | **<0.001** | | **<0.001** |
| Grade 1[a] | 0.97 (0.63–1.50) | 0.891 | 1.10 (0.71–1.73) | 0.668 |
| Grade 2[a] | 1.27 (0.85–1.89) | 0.240 | 1.38 (0.92–2.06) | 0.120 |
| Grade 3[a] | 3.66 (2.59–5.17) | **<0.001** | **3.90 (2.75–5.54)** | **<0.001** |
| Maximum grade of foraminal stenosis | | **<0.001** | | 0.614 |
| Grade 1[a] | 0.64 (0.46–0.90) | **0.009** | | |
| Grade 2[a] | 1.22 (0.84–1.77) | 0.297 | | |
| Grade 3[a] | 1.27 (0.90–1.80) | 0.171 | | |
| Grade 2 or 3 of maximal foraminal stenosis | 1.56 (1.20–2.01) | **0.001** | **1.59 (1.21–2.09)** | **0.001** |
| The number of central stenotic levels | | **0.001** | | 0.216 |
| 1[b] | 2.02 (1.42–2.86) | **<0.001** | | |
| 2[b] | 1.97 (1.35–2.88) | **<0.001** | | |
| 3[b] | 2.38 (1.52–3.73) | **<0.001** | | |
| 4[b] | 2.42 (1.24–4.71) | **<0.001** | | |
| 5[b] | 1.61 (0.44–5.90) | 0.469 | | |
| The number of foraminal stenotic levels | | 0.697 | | |
| 1[b] | 0.87 (0.64–1.19) | 0.394 | | |
| 2[b] | 0.98 (0.69–1.38) | 0.911 | | |
| 3[b] | 1.19 (0.71–1.98) | 0.515 | | |
| 4[b] | 1.49 (0.56–3.96) | 0.429 | | |
| 5[b] | 0.44 (0.05–4.28) | 0.479 | | |

[a] Odds compared to grade 0, [b] Odds compared to 0 level

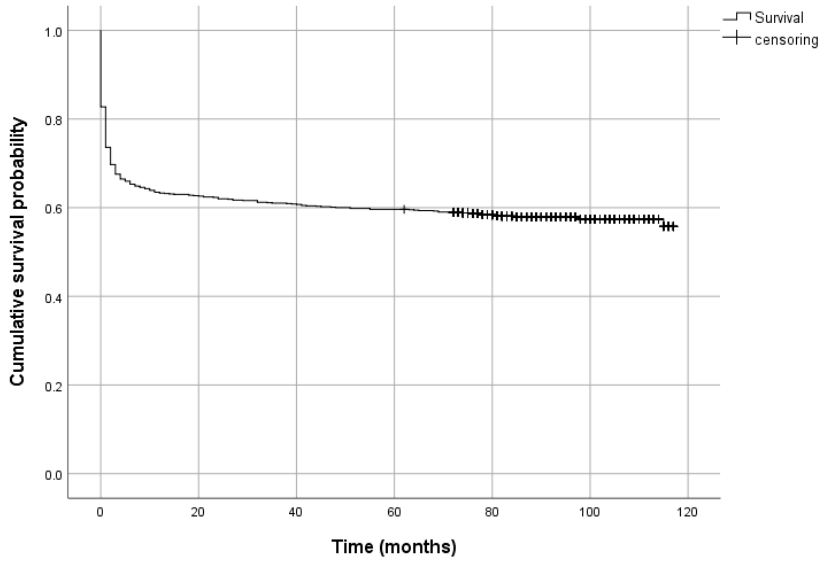


Figure 4. Kaplan-Meier survival curve of overall LSS patients

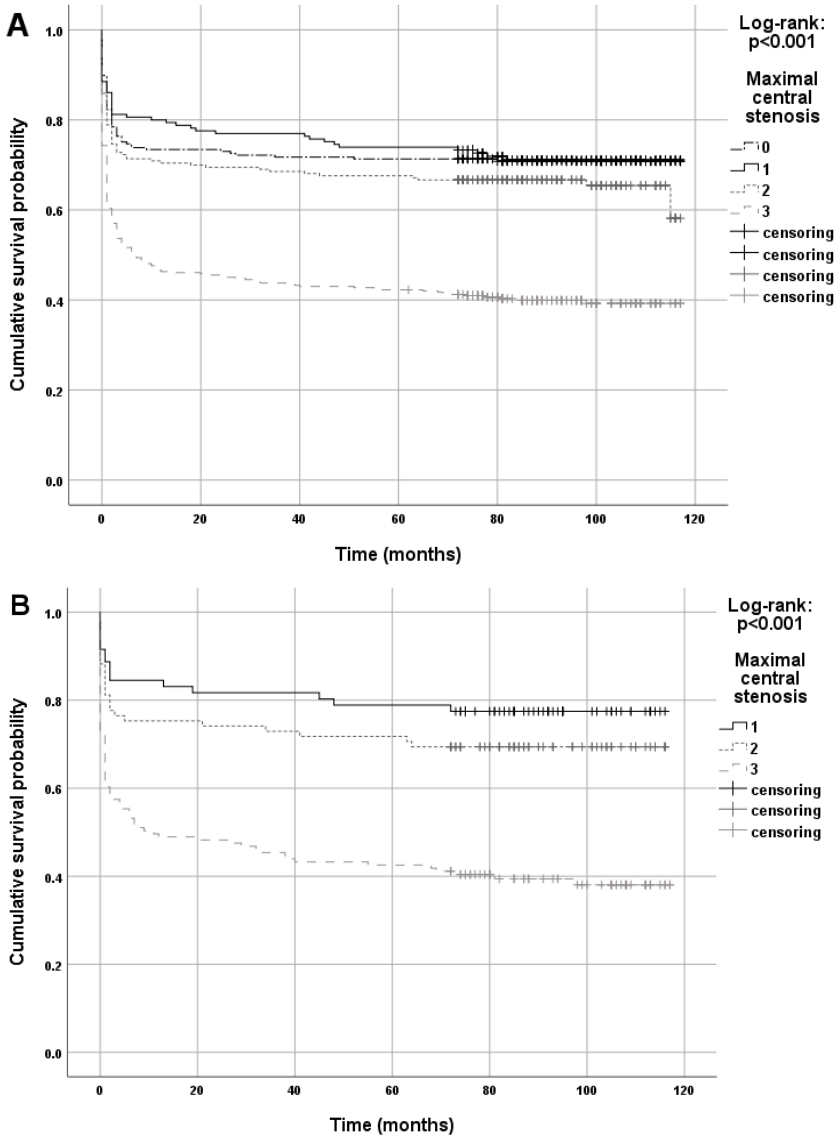


Figure 5. Kaplan-Meier survival curves according to the grade of maximal central stenosis with concomitant foraminal stenosis (A) and without concomitant foraminal stenosis (B). Significant difference was observed in the survival curve between grades 3 maximal central stenosis and the others.

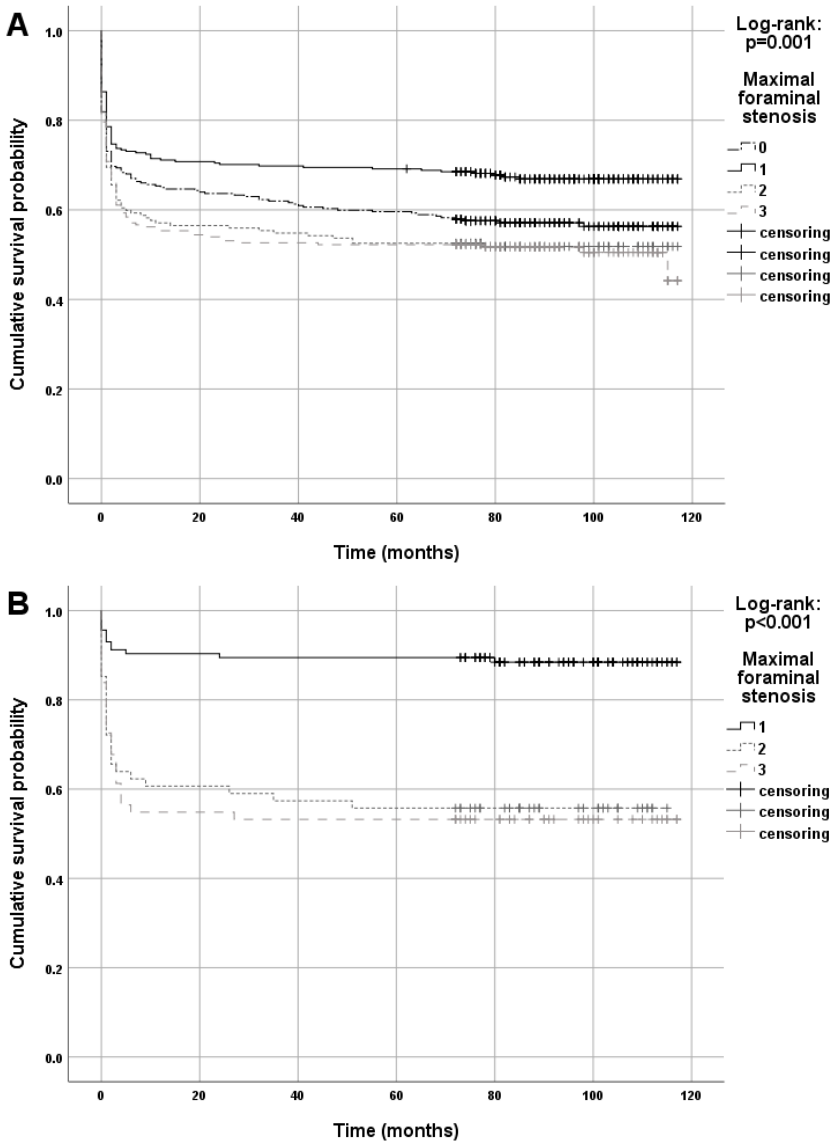


Figure 6. Kaplan-Meier survival curves according to the grade of maximal foraminal stenosis with concomitant central stenosis (A) and without concomitant central stenosis (B). Significant difference was observed in the survival curve between grades 1 maximal foraminal stenosis and the others.

# Chapter 4. Discussion

The present study showed that the grades of maximal central and foraminal stenosis on initial MRI are risk factors for subsequent surgery in patients with LSS in the course of the disease. During the mean 7.6 years of follow-up period, surgical probabilities in grade 1, 2 and 3 maximal central stenosis were 22.5%–45.0%, 22.2%–41.7% and 57.9%–62.3%, respectively, depending on the concomitant grades of maximal foraminal stenosis. Surgical probabilities in grade 2 and 3 maximal foraminal stenosis were 22.2%–62.3% and 33.3%–57.9%, respectively, depending on the concomitant grades of maximal central stenosis. Grade 3 maximal central stenosis showed the highest OR (3.90) for surgical treatment and the highest percentage (57.9%–62.3%). These results imply that the natural history of patients with LSS in the view of the surgical treatment would depend on the grades of maximal central and foraminal stenosis on MRI.

These findings are consistent with those from Schizas' study, which showed that a greater proportion of patients with severe stenosis based on MRI findings underwent surgery compared to the mild group [16]. Some studies have reported contrasting results, indicating that the severity of stenosis on MRI had no predictive value for the natural history of LSS [3, 4]. However, they used the anterior–posterior diameter of the spinal canal on MRI as a radiological parameter, which was not adequate to accurately assess the degree of neural tissue impingement. Therefore, the morphological classification that reflects neural impingement would be more suitable in both prediction of the disease progress and assess of the severity of stenosis.

A critical point of this study is that we did not access any conservative treatment which patients had taken during the follow-up period. This might be an inherent limitation from retrospective design and long-term follow-up study. However, there has been no study which advocates any conservative can make a change of natural history in LSS. Therefore, this absence of information about conservative treatment would not influence the present conclusion. Likewise, any clinical outcome such as the level of pain and/or disability due to LSS was not assessed during the follow-up period. It might be inappropriate to judge the natural course of LSS using MRI alone, without considering clinical symptoms and other factors, because the surgical decision is made by the complex mechanism both in patients and surgeons. However, it is well-known that the symptoms of LSS fluctuate with the time of its natural course even without change of stenosis [17-19]. Therefore, it might be plausible that the patients who underwent surgical treatment would have progressively increased pain intensity and severe disability in this study and

vice versa.

Maximal central stenosis of grade 3 and maximal foraminal stenosis of grades 2 or 3 were significant risk factors for surgical treatment. These observations are congruent with previous studies in which LSS patients with severe stenosis on MRI showed no improvement in VAS score during course of disease [9] and patients with block stenosis at myelography eventually needed surgical decompression [10]. Surgical probability in grade 3 maximal central stenosis (57.9%–62.3%) were higher than those in grade 2 and 3 maximal foraminal stenosis (22.2%–62.3% and 33.3%–57.9%, respectively) (Table 2). Grade 3 maximal central stenosis showed the higher OR (3.90) of surgical treatment than grade 2 and 3 maximal foraminal stenosis (1.59) (Table 3). These findings suggest that surgical probability is more affected by severe central stenosis than by severe foraminal stenosis. But these findings may mean that central stenosis is easier to diagnose and easier to operate. There was no significant difference in surgical probabilities between grades 1 and 2 maximal central stenosis regardless of the grade of foraminal stenosis in subgroup analysis (Table 2) and no significant difference in the survival curve among grades 0, 1 and 2 of maximal central stenosis (Fig. 5). The possible explanation for those findings is that clinical symptom or neurological impairment of patients of grade 1 maximal central stenosis might have not differed from grade 2 maximal central stenosis, which is consistent with Andrasinova's study showing no significant difference in Neurological Impairment Score in LSS between grades B and C of Schizas morphologic classification [5].

The slope of the plateau part of the survival curve is similar among each grade of stenosis, which means that the grade of stenosis on MRI does not affect the symptoms indicating the surgery. The plateau after initial steep drop for each grade in survival curve can be found in previous study. In Amundsen's partially randomized 10-year follow-up study about natural history of LSS, this plateau could had been observed from that study showing that crossover from conservative to surgical treatment occurred during initial period of 3 to 27 month and treatment result during the final 6 years of the follow-up period were relatively stable [3]. This initial crossover and stable period of final 6 year can explain the initial steep drop and plateau of survival curve in our study, and this imply that the initial response of conservative treatment is important to determine the patients' treatment plan. Thus, the initial treatment response could be regarded more important for surgical decision than the later symptom which is represented by the slope of the plateau part of the survival curve similar among each grade of stenosis (Fig. 5, 6). The initial steep drop in the survival curve would be associated with the

place where this study was conducted, which was the tertiary hospital and almost all patients had had adequate conservative treatment before inclusion of the present study. The plateau of the survival curve after initial drop and no intersection of survival curves could means that disease progression of LSS represent generally slow and benign nature. These findings were consistent with previous studies which have advocated the benign nature of LSS progression [3, 4].

The present study has some limitations. Due to the inherent shortcoming of the retrospective study design, we did not assess other factors that might affect the surgical decision including the socioeconomic status, race, ethnicity, and clinical symptoms. However, in the country where this study was conducted, the research population consisted of a single race and a single ethnic group. In addition, all individuals are enrolled in the national medical insurance, and the burden of treatment costs would not differ considerably according to the socioeconomic status. In the case of a small number of patients who underwent surgery at other hospitals, there is possibility for effect of prejudice of doctors and patients, such as determining surgery based on imaging findings of severe stenosis. Likewise, the clinical symptoms of the included patients might have fluctuated during the long-term follow-up period, with patients with worsening back pain or leg pain undergoing surgical treatment and vice versa. Because the surgical decisions in this study were made under informed consent or preference-based shared decision-making process rather than the surgeon's sole decision, patients who underwent surgical treatment likely had severe and refractory symptoms despite receiving conservative treatments before surgery. Thus, the present results would help physicians to estimate the surgical probability during the follow-up period, based on the stenotic severity on initial MRI.

# Chapter 5. Conclusions

In conclusion, this study highlights the difference in the surgical probabilities of LSS depending on the severity of stenosis. Altogether, 57.9%–62.3% of patients with grade 3 maximal central stenosis eventually underwent surgery during the mean 7.6 years of follow-up period. Therefore, the severity of stenosis on MRI at the time of diagnosis can predict the probability of surgical treatment, and the natural history in the view of surgical treatment depends on the grade of stenosis.

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# 감사의 글

우선 항상 옆에서 응원하고 적극적인 지지를 보내주는 나의 부인 노예리에게 무한한 감사함 및 사랑을 표합니다. 또한 소위 '논알못'(논문을 알지 못하는 자)였던 저를 논문 작성의 세계로 이끌어주신 김호중 선생님, 그리고 바쁘신 와중에도 저의 석사논문심사를 맡아주신 장봉순선생님, 김치헌선생님께도 무한한 감사함 및 존경을 표합니다. 군대에 복무하며 조금씩 작성한 논문이 결국에는 SCI급 학회지에 출간되고, 무사히 석사까지 마치게 되어 감개 무량함을 느낍니다. 앞으로도 정진하여 의학 발전에 도움이 되는 의학도가 되도록 노력하겠습니다. 다시 한번 도움을 주신 모든 분들께 감사하다는 말씀을 드리며 글을 마치겠습니다.

# 국문초록

배경: 요추 척추관 협착증 환자의 진단 당시의 초기 자기공명영상촬영(MRI)에서 협착의 정도를 평가하는 정성적 등급 체계로 평가한 방사선학적 중증도에 따른 보존적 치료 실패 및 수술 가능성을 추정하고자 하였다.
방법: 후향적 관찰 연구로서 2011년부터 2014년까지 우리 병원에서 요추 척추관 협착증 진단을 받은 총 1,008명의 환자를 평균 7.6년(5.17-9.8년) 동안 추적 관찰했다. 이성훈 등이 보고한 정성적 등급 시스템을 사용하여 진단 당시의 초기 MRI에서 중심 협착 및 추간공 협착의 중증도를 조사하였고, 추시 기간 중 환자의 수술적 치료 여부를 조사했다. 로지스틱 회귀 모델로 수술의 위험 요소를 식별하고자 하였다.
결과: 평균 추시 기간 7.6년 동안 3등급의 최대 중심 협착증인 환자들이 가장 높은 비율(57.9%-62.3%)로 수술적 치료를 받게 됨을 확인하였고, 이들에게 동반된 추간공 협착증에 따른 수술 확률에는 큰 차이가 없었다. 2등급과 3등급의 최대 추간공 협착증에서 수술을 받게 될 확률은 동반되는 중심 협착에 따라 각각 22.2%-62.3% 및 33.3%-57.9%였다. 3등급의 최대 중심 협착증(교차비, 3.90)과 2등급 또는 3등급의 최대 추간공 협착(교차비, 1.59)이 보존적 치료 실패의 유의한 위험인자였다.
결론: 높은 등급의 최대 중심 및 추간공 협착은 보존적 치료 실패의 위험인자였다. 진단 당시의 초기 MRI에서 협착증의 정도에 따라 수술적 치료의 가능성을 예측할 수 있으며, 이러한 결과는 요추 척추관 협착증의 자연사가 최대 중심 및 추간공 협착의 등급에 따라 다르다는 것을 시사한다.

주요어 : 요추 척추관 협착증; 자연사; 수술적 치료의 결정; 자기 공명 영상; 정성적 등급 체계
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