



Contents lists available at ScienceDirect

Journal of Orthopaedic Science

journal homepage: <http://www.elsevier.com/locate/jos>

Original Article

A comparative study of 2-year follow-up outcomes in lumbar spinal stenosis patients treated with physical therapy alone and those with surgical intervention after less successful physical therapy

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ARTICLE INFO

Article history:

Received 31 August 2017
 Received in revised form
 22 December 2017
 Accepted 9 January 2018
 Available online xxx

ABSTRACT

Background: The efficacy of physical therapy for patients with lumbar spinal stenosis (LSS) has been reported only for the short term, and few reports have compared outcomes of surgical treatment with nonsurgical treatment after physical therapy. The purpose of this study was to assess 2-year outcomes of LSS patients treated with surgery or under follow-up observation after physical therapy for 6 weeks.

Methods: Patients presenting with neurogenic claudication, radiologically-confirmed central LSS affecting both legs and refractory symptoms to pharmacotherapy of more than 3 months were enrolled. Patients were treated with manual therapy, stretching and strengthening exercises, and body weight-supported treadmill walking once a week for 6 weeks. Clinical outcomes were measured using the Zurich Claudication Questionnaire (ZCQ), visual analog scale of low back pain, leg pain, and numbness, the Japanese Orthopedic Association Back Pain Evaluation Questionnaire and the SF-36. Two years after physical therapy, patients were classified into the observation group (Group I) or the surgery group (Group II), whose patients failed to respond to physical therapy and wanted to undergo surgery.

Results: Thirty-eight patients were enrolled; 28 had complete data at 2 years: 21 and 7 in Groups I and II, respectively. Group II had a higher body mass index (BMI) than Group I. There were no significant differences in clinical outcomes at baseline. Six weeks after physical therapy, Group I had significantly better outcomes for symptom severity and physical function on the ZCQ subscales, physical functioning and bodily pain on the SF-36 subscales. These outcomes in Group I were maintained or improved and did not differ significantly between groups at 2-years. However, the physical function on the ZCQ subscales was improved in Group II more than those in Group I (mean difference -0.6 ; 95% CI: -1.2 to -0.03 , $P < 0.05$) at 2 years.

Conclusions: At 2 years, the outcomes except for the change in physical function score in the ZCQ subscale did not differ significantly between patients who had undergone surgery and those who avoided surgery.

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1. Introduction

A previous systematic review comparing surgical versus nonsurgical treatment for lumbar spinal stenosis (LSS) reported that surgery led to better results for pain, disability, and quality of life, although not for walking ability. However, in studies of

nonsurgical treatment, different modalities such as bracing, physical therapy, and epidural steroid injection were applied, but not in any systematic or methodical way [1]. In the Spine Patient Outcomes Research Trial (SPORT) [2], the largest randomized, controlled trial (RCT) to compare surgical and nonsurgical treatment of LSS, patients who received nonsurgical treatments were treated using “usual care,” which was defined as providing recommendations for active physical therapy, education, or counselling with home exercise instruction, and/or nonsteroidal anti-inflammatory medications. In the SPORT, no standardized

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<https://doi.org/10.1016/j.jos.2018.01.003>

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protocol was used for the nonsurgical treatments, and only 37% of patients in the nonsurgical group received physical therapy within 6 weeks [3]. The patients who received physical therapy had higher self-ratings of improvement and were less likely to cross over to surgery than those who did not undergo physical therapy.

Several researchers have reported on the efficacy of physical therapy for patients with LSS. This therapy includes flexion exercises, strengthening exercises, aerobic conditioning such as body weight-supported treadmill walking and cycling, and physical therapy treatments such as ultrasound, hot packs, and transcutaneous electrical nerve stimulation [4]. A recent systematic review of physical therapy suggested that exercise is significantly better than no exercise and that cycling and body weight-supported treadmill walking have similar effects [4]. The addition of a physical therapy modality to exercise has no statistically significant effect on outcomes. However, the efficacy of physical therapy for patients with LSS has been reported only for the short term, and few reports have compared outcomes of surgical treatment with those of nonsurgical treatment after physical therapy. The purpose of this retrospective study was to assess the 2-year follow-up outcomes of LSS patients treated with surgery or under follow-up observation after physical therapy for 6 weeks.

2. Materials and methods

This retrospective study of prospectively collected data was conducted at the Spine Care Center, Wakayama Medical University Kihoku Hospital. This study was reviewed and approved by the Institutional Review Board at Wakayama Medical University (No. 1014). After screening for eligibility, all patients provided informed written consent.

Patients presenting with symptoms, signs, and radiological findings of central LSS were enrolled from April 2011 to October 2012. Screening for eligibility was made by one of two orthopedic spine surgeons in our institute. The inclusion criteria included the presence of bilateral pain and/or numbness in the lower extremities with or without low back pain, the presence of neurogenic claudication, magnetic resonance imaging (MRI) findings consistent with central LSS with degenerative changes, over 50 years of age, and a history of ineffective responses to pharmacotherapy for more than 3 months. The exclusion criteria were previous spine surgery, treatment with epidural steroid injection or selective nerve root block, degenerative scoliosis, spondylolisthesis with >3 mm of slippage, loss of bowel or bladder control, trauma, osteoporosis, osteoarthritis of the knee and/or hip, peripheral artery disorders, diabetes mellitus, cognitive impairment, or a history of psychiatric illness.

Thirty-eight consecutive patients fulfilled the inclusion and exclusion criteria and were enrolled. Patients were evaluated prospectively at 6 weeks and 2 years after the intervention on the basis of a structured protocol established before patient enrollment [5]. Physical therapy was prescribed for 6 weeks, with a frequency of 1 visit per week for a 20–30-min session. The following treatments were administered during the physical therapy session: manual therapy, flexion and strengthening exercises for the lumbar, abdominal, and leg muscles under the supervision of a physical therapist, and body weight-supported treadmill ambulation. In addition to the physical therapy sessions, all patients were asked to take a daily walk and to perform a home exercise program comprising flexion and strengthening exercises over a 6-week period. The aim of our physical therapy program was to help patients acquire exercise habits and increase their physical activity during the 6-week treatment period. Additional information about this program is available in a previous publication [5]. Patients were allowed to receive pharmacotherapy including limaprost and a

nonprotein extract derived from the inflamed skin of rabbits inoculated with vaccinia virus (Neurotropin, Nippon Zoki Pharmaceutical Co., Osaka, Japan). Limaprost, a prostaglandin E1 derivative, is a potent vasodilator and antiplatelet agent, and is used to treat the symptoms of LSS in Japan [6]. Neurotropin is widely used in Japan for the treatment of neuropathic pain. The analgesic effect of Neurotropin is considered to be mediated by activation of descending pain–inhibitory pathways via the serotonergic and noradrenergic systems projecting from supraspinal sites to the spinal dorsal horn [7]. If patients failed to respond to physical therapy for 6 weeks and wanted to undergo surgery, decompression surgery was performed. No patients had spinal fusion.

At baseline, the patients were asked about their demographic background, including age, gender, body mass index (BMI), and duration of symptoms. The severity of dura mater compression was evaluated from the MRI findings of the lumbar spine. MRI findings were examined using a 7-grade classification based on the morphology of the dural sac, as observed on T2 axial magnetic resonance images based on the rootlet/cerebrospinal fluid ratio [8]. Two orthopedic spine surgeons who were certified as specialists by the Japanese Orthopedic Association and Japanese Society for Spine Surgery and Related Research Spine determined the grade of the dura mater compression and reached consensus for all patients.

Clinical outcomes were measured using the Zurich Claudication Questionnaire (ZCQ) [9,10], a visual analog scale (VAS) of low back pain, leg pain, and numbness [11], the Japanese Orthopedic Association Back Pain Evaluation Questionnaire (JOABPEQ) [12], the Medical Outcomes Study 36-item Short-Form General Health Survey (SF-36) [13,14], the Roland–Morris Disability Questionnaire (RDQ) [15,16], and the Self-Rating Questionnaire for Depression (SRQ-D) [17,18] at baseline, immediately after completion of the 6-week program, and 2 years after the intervention. Scores on the ZCQ symptom severity subscale range from 1 to 5. Scores on the physical function subscale range from 1 to 4, with higher scores indicating more severe symptoms. Scores on the satisfaction subscale range from 1 to 4, with higher scores indicating more satisfaction with treatments. The VAS ranges from 0 (no pain) to 100 (the worst imaginable pain) and is measured in millimeters, with higher scores indicating greater pain intensity. The JOABPEQ comprises five domains: pain-related disorders, lumbar spine dysfunction, gait disturbance, social life dysfunction, and psychological disorders. The scores for the JOABPEQ range from 0 to 100, with a higher score indicating better health status. The SF-36 comprises eight factors: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health. The range of scores for each domain is 0–100 points, with lower scores indicating greater disability. The RDQ score ranges from 0 to 24, with higher scores indicating greater disability. The SRQ-D score ranges from 0 to 36, with higher scores indicating more symptoms of depression. Compliance with the home exercise program was measured using a self-report questionnaire. The completed questionnaires were collected, and two authors who were not involved in the treatments checked to ensure that no questionnaire had been left unanswered.

Two years after the physical therapy, patients were classified into an observation group (Group I) or a surgery group (Group II), in which patients wanted to undergo surgery after physical therapy. The mean timing of the surgery was 4.3 months (range: 1–10 months) after the physical therapy. Between-group comparisons were made using Student's *t* test for parametric variables and the Mann–Whitney *U* test for nonparametric variables. Changes in clinical outcomes were also assessed based on the percentage in each group that reached a threshold of minimal clinically important difference (MCID). The MCID for the ZCQ symptom severity and

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