A randomized study protocol of microendoscopic versus open discectomy in treatment of lumbar disc herniation

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Abstract

Background: Lumbar disk herniation (LDH) is one of the main causes of discogenic low back pain. However, the evidence comparing different approaches for discectomy has lacked definitive conclusions, with conflicting results regarding the benefit of minimally invasive versus open techniques for LDH. We are now conducting a randomized controlled trial to figure out whether or not microendoscopic discectomy yields better clinical outcomes and causes less surgical trauma than open surgery.

Methods: This prospective, randomized, single-blind, controlled, superiority clinical trial was approved by the institutional review board in the People’s Hospital of Jianyang City. The conduct of this study followed the Declaration of Helsinki principles and the reporting of this study adhered to the Consolidated Standards of Reporting Trials guidelines for randomized controlled trials. Subjects were randomized into 2 groups as follows: open surgery and microendoscopic group. The outcomes included pain score, functional outcome, satisfaction rate, radiological outcomes, and complications. The statistical analyses in this study were performed using the Statistical Package for the Social Sciences 20.0 software. \( P < .05 \) was accepted as statistically significant.

Results: The hypothesis was that the open technique would achieve similar clinical outcomes as compared to the microendoscopic technique in LDH.

Trial registration: This study protocol was registered in Research Registry (researchregistry5708).

Abbreviations: LDH = lumbar disk herniation; VAS = visual analogue scale.

Keywords: lumbar disk herniation, open discectomy, microendoscopic discectomy, protocol

1. Introduction

Lumbar disk herniation (LDH), one of the most common conditions for which patients visit the Department of Orthopedics, always carries a series of signs and symptoms. It is one of the main causes of discogenic low back pain and reported to affect 60% to 80% of people during their lifetime.\[1–3\] Lumbosacral radiculopathy caused by the bulge of the nucleus pulposus and the secondary inflammatory reaction is the most challenging problem. Surgical intervention is required in patients whose symptoms fail to improve with conservative treatment.\[4–6\]

There are 2 main surgical modalities for intervertebral disc surgery: microendoscopic and open discectomy. Although various surgical options exist for lumbar disk herniation patients who do not respond to conservative treatment, open discectomy still remains a standard method.\[7,8\] The traditional discectomy through laminotomy and microdiscectomy has obtained satisfactory results, but most experienced spine surgeons now prefer use of minimally invasive procedures that cause less trauma and lead to faster rehabilitation, such as percutaneous transforaminal endoscopic discectomy and microendoscopic discectomy, which are widely performed in treating LDH and achieve satisfactory clinical outcomes.\[9–12\] However, some patients complain of persistent or recurrent radiating pain after minimally invasive discectomy, which can be accompanied by recurrence of the disc herniation.\[13\]

Previously, several observational studies have also tried to compare the efficacy and safety of these 2 procedures. However, the evidence comparing different approaches for discectomy has lacked definitive conclusions, with conflicting results regarding the benefit of minimally invasive versus open techniques for LDH.\[14–18\] We are now conducting a randomized controlled trial to figure out whether or not microendoscopic discectomy yields better clinical outcomes and causes less surgical trauma than open surgery. The hypothesis was that the open technique would achieve similar clinical outcomes as compared to the microendoscopic technique in LDH.

1Y and ZL contributed equally to this work.

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2. Materials and methods

2.1. Study Design

This prospective, randomized, single-blind, controlled, superiority clinical trial was registered in Research Registry (researchregistry5708) and approved by the institutional review board in the People's Hospital of Jianyang City (YNJY06940021). The conduct of this study followed the Declaration of Helsinki principles and the reporting of this study adhered to the Consolidated Standards of Reporting Trials guidelines for randomized controlled trials. The flowchart of this trial is shown in Figure 1.

2.2. Participants

The inclusion criteria for patients in this study included: age 20 to 90 years; persistent radicular pain lasting for >6 to 8 weeks; disc herniation confirmed by MRI single-level herniation, adjacent bisegmental herniation, desiccated disc with body root; entrapment/lateral canal stenosis; unilateral herniation was larger than one-third of the spinal canal diameter with concomitant lateral recess stenosis or “equestration.” Exclusion criteria were: <2 level disc herniation; cauda equina syndrome; spondyloytic or degenerative spondylolisthesis; spinal canal stenosis; pregnancy; severe somatic or psychiatric illness.

2.3. Randomization

Randomization was done by a secretary using a computer-generated randomization list (Research randomizer, www.randomizer.org) in a 1:1 ratio with 20 numbers in each block. Every participant received a consecutive study number from 1 to 69 and received the treatment assigned according to the randomization list. All clinical personnel and outcome assessors were blinded to the intervention. The randomization key was first broken when all enrolled patients had completed the study. After discharge, the participant’s personal information was eliminated from the study number and was therefore not traceable back to the patients.

2.4. Techniques

2.4.1. Open surgery group. Without the use of operating microscope, 8 to 10cm medline skin incision was centered over the affected level after fluoroscopic verification. Using cutting diathermy dorso-lumbar fascia was incised, then stripping the paraspinal muscles off the spinous processes and lamina was

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Figure 1. Flow of patients through the trial.
performed until the facet joints laterally, then muscles were retracted laterally using a self-retaining retractor. Using Kerri-
son’s Rongeur we did hemilaminectomy depending on the
preoperative planning then locating and removal of the extruded
or the sequestered disc material.

2.4.2. Microendoscopic group. An 18-mm tubular retractor
was inserted over the sequential dilators that were inserted over
a guide wire directed to superior lamina of the desired level then
the rigid endoscope was inserted into the tubular retractor.
Partial flavectomy was performed after laminotomy in which we
limit the excision of the Ligamentum flavum enough to see the
lateral edge of the dural sac and the traversing nerve root then
retract them both medially with their covering of ligamentum
flavum, then perform discectomy. In almost all cases we found
the large extrusion directly under the ligamentum flavum. We
could search for caudal sequestration by placing the endoscope
cephalic and with the help of angled ball probe we could retrieve
part or all of the sequestration by sweeping under the dural sac
or posterior longitudinal ligament or searching into interverte-
bral foramen and lateral recess then we pull it out with the help
a rongeur.

2.5. Clinical Outcome Measures

The outcomes included pain score, functional outcome, satisfac-
tion rate, radiological outcomes, and complications. Pain score
and functional outcomes were assessed by using a visual analogue
scale (VAS, 0-10) and the Oswestry Disability Index (0-100%),
respectively. Subjective surgical satisfaction rate (%) was assessed
by asking the patient, “How satisfied were you with this
operation?” Pre- and postoperative data were assessed by clinical
charts and operation records. Radiographs were assessed
preoperatively and at the 2-year follow-up.

2.6. Sample Size Calculation

The sample size calculation was based on a pilot study that we
conducted on eighteen patients (whose data were not included in
the present study). In this previous study, the mean difference and
standard deviation of the VAS scores after the operation at 1 year
between the open and microendoscopic groups were 0.52 and
0.21, respectively. From this, it was determined that 60 subjects
would be required to reach a α value of 0.05 and a power of
90%. It was estimated that the attrition rate due to canceled
surgery or reasons of late patient ineligibility could be up to 20%
and, therefore, to account for this, the final sample size selected
was n=140 (70 per group).

2.7. Statistical analysis

The statistical analyses in this study were performed using the
Statistical Package for the Social Sciences 20.0 software.
Continuous variables were presented in the form of mean ±
standard deviation or error. The Kolmogorov-Smirnov normality
test was used to assess continuous variables. Group comparisons
on the variables that showed normal distribution were performed
using one-way analysis of variance. Mann–Whitney U variance
analysis was used for discrete numerical variables that did not
show normal distribution. Relationships between the categorical
variables were determined by preparing crosstabs and using the
χ² test. P < 0.05 was accepted as statistically significant.

3. Discussion

Low back pain has become one of the most serious public health
problems, with a lifetime prevalence as high as 84% and the
prevalence of chronic low back pain is about 23%, with 11% to
12% of the population being disabled by low back pain.[4–7] To
date, the factors that eventually cause pathological progression
have not been determined. However, along with recent economic
development, living, environmental, and working conditions
have substantially changed in China. Lumbar disc herniation is
one of the most common spinal degenerative disorders leading to
LBP associated with radiculopathy. On the other hand, some
studies found that disc herniation was actually common in
asymptomatic people as well. Inflammatory response has been
acknowledged to be important in the process of disc degeneration
and may play an important role in pain generation.[12–14]

We are now conducting a randomized controlled trial to figure
out whether or not microendoscopic discectomy yields better
clinical outcomes and causes less surgical trauma than open
surgery. The hypothesis was that the open technique would
achieve similar clinical outcomes as compared to the micro-
endoscopic technique in LDH. The main limitation of the present
study was the inability to blind both the participants and the
physicians to comparisons between peripheral nerve blockade
and periarticular injection. This lack of blindness may have
introduced some risk of bias from both the patients and the
physicians. The outcome assessments from the adjudicators and
all the statistical analyses were conducted in a blinded manner.

Author contributions

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