Is it really necessary going all over the top in patients with symptomatic lumbar canal stenosis?

Non-inferiority of osseous decompression of the lumbar canal until normalization of epidural pressure compared to conventional open laminectomy in patients with symptomatic lumbar canal stenosis.

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Juan Pablo Castaño Montoya
Universidad Complutense de Madrid
+34-669345474
juanpablo.castano@salud.madrid.org

1. Terminology

- **Pressure-guided laminectomy (PGL):** Bone resection of the lamina and ligamentum flavum until epidural pressure reaches a normal value in the stenotic segment.
- **Non–pressure-guided laminectomy (NPGL):** Complete resection of both the lamina and ligamentum flavum in the stenotic segment.

2. Introduction

Lumbar spinal canal stenosis is a prevalent and disabling cause of low back and lower limb pain in the elderly, and it is estimated to affect over 103 million people worldwide. (1) It significantly impairs patients' quality of life due to the presence of pain and gait disturbances, impacting social functioning and contributing to the development of psychological disorders. (2) Three main hypotheses have been proposed to explain the phenomenon of neurogenic claudication: the postural theory, the ischemic theory, and the venous stasis theory. However, the precise mechanism by which nerve root compression causes the typical clinical presentation of lumbar stenosis remains incompletely understood. (3)

A wide range of therapeutic options exists for the management of lumbar spinal stenosis, from conservative treatments such as physical therapy and neuromodulators to percutaneous procedures like epidural injections, and finally surgical approaches ranging from decompression to spinal fusion (1,4). Current surgical techniques focus on decompressing the dural sac to address a mechanical compression problem. These procedures can be performed through open surgery or minimally invasive methods using endoscopic or tubular approaches.

A study conducted at this hospital by Carrascosa et al., with results published in 2020 and 2023, found that in patients who underwent canal decompression via laminectomy with radiologic confirmation of the dural sac decompression area, clinical improvement was not associated with the postoperative area of the spinal canal or thecal sac (5,6). Similar findings have been reported in other studies, emphasizing the poor clinicoradiological correlation in this condition, which suggests that the pathogenesis of lumbar spinal stenosis may not be solely mechanical, and that additional contributing factors may be involved (7–9).

Our research group has developed an interest in identifying these additional factors and has proposed a new theory to explain neurogenic claudication. We hypothesize that epidural pressure is elevated in stenotic segments compared to healthy ones and plays a role in the disease's pathophysiology, either by impairing cerebrospinal fluid (CSF) flow or by causing local ischemia of the cauda equina nerve roots. This is supported by evidence of increased epidural pressure

in patients with spinal stenosis compared to healthy controls, as well as the observation of dynamic epidural pressure changes in patients with neurogenic claudication (10–12).

This theory supports the use of minimally invasive procedures, which aim to decompress the canal through small access corridors without requiring open surgery, extensive dissection of the lumbar musculature, or resection of bone and ligamentous structures. In this way, it is possible to minimize the risk of secondary spinal instability by performing decompression through a unilateral approach while preserving midline structures such as the supraspinous and interspinous ligaments and the paravertebral musculature (13–16).

Based on the aforementioned rationale, this study aims to evaluate the non-inferiority of pressure-guided lumbar canal decompression—until epidural pressure normalizes in the stenotic segment—compared to conventional open laminectomy without pressure guidance. Both groups will be assessed using clinical scales and radiologic imaging to determine clinical improvement. We hope that the results of this study will support the theory of lumbar epidural hypertension as a potential etiological factor in neurogenic claudication.

3. Hypothesis

The null hypothesis is that non-inferiority of pressure-guided laminectomy compared to non–pressure-guided laminectomy cannot be demonstrated in patients diagnosed with symptomatic lumbar spinal stenosis.

The alternative hypothesis is that osseous decompression of the lumbar canal until epidural pressure normalization is not inferior to conventional open laminectomy in achieving clinical improvement in patients with symptomatic lumbar spinal stenosis, as measured by the Zurich Claudication Questionnaire (ZCQ).

4. Objectives

4.1. General objective

To assess whether osseous decompression of the lumbar canal until normalization of epidural pressure is not inferior to conventional open laminectomy in achieving clinical improvement in patients with symptomatic lumbar spinal stenosis, as measured by the clinical severity subscale of the Zurich Claudication Questionnaire (ZCQ).

4.2. Specific objetives

- To characterize the demographic variables of patients undergoing surgical treatment for lumbar spinal stenosis.
- To compare the clinical response of patients treated using the two different surgical techniques.
- To determine the extent of osseous decompression performed using imaging techniques.
- To evaluate the complications associated with the surgical procedures.

5. Materials and methods

A single-blind, randomized, controlled non-inferiority clinical trial is proposed to compare the effectiveness of total osseous decompression of the lumbar canal until normalization of epidural pressure versus conventional open laminectomy in patients with symptomatic lumbar spinal stenosis.

5.1. Study and reference population

The study will include patients with chronic low back pain and/or lower limb pain secondary to lumbar spinal canal stenosis, who are treated at the San Carlos Clinical Hospital and attend consultations in the Neurosurgery Department. Given the vulnerability of the study population, an a priori sample size calculation will be performed to ensure the objectives can be met and a representative sample of this patient population can be obtained.

To improve the statistical reliability of the study results, a minimum sample of 24 subjects has initially been selected. The study will be conducted in the Neurosurgery Department at the San Carlos Clinical Hospital in Madrid.

5.2. Inclusion and exclusion criteria

Inclusion criteria:

- Age over 50 years.
- Surgical indication determined by:
  - Low back and/or lower limb pain lasting more than 3 months.
  - Pain refractory to conservative medical treatment (analgesics, physical therapy, epidural block).
  - Clinical criterion for neurogenic claudication defined as a score ≥11 on the N-CLASS scale (Annex 1). (17)
  - Preoperative MRI confirming spinal canal stenosis. (18)
- Patient agrees to undergo the proposed surgical intervention.
- Patient consents to participate in the study by signing the informed consent form.

Exclusion criteria:

- Foraminal or lateral recess stenosis.
- Symptomatic disc herniation at the surgical level.
- Spondylolisthesis greater than Meyerding Grade I (vertebral displacement >25%) or spondylolysis.
- Radiological instability defined as sagittal plane displacement >5 mm on dynamic flexion-extension spinal X-rays.
- Scoliosis with a Cobb angle >30º.
- Compression fracture at the target surgical level.
- Previous surgery at the same level to be treated.
- Prior infection at the target level.
- Contraindication for magnetic resonance imaging.
- Diagnosis of major depression or dysthymia according to DSM-V criteria. (19)

5.3. Withdrawal criteria

- The patient requests to withdraw from the study.
- Inability to follow the assigned surgical protocol (e.g., intraoperative necessity to convert to a different surgical technique due to unforeseen findings).
- Medical events that contraindicate surgical intervention.
- Withdrawal of informed consent by the patient.

5.4. Dropouts and management of withdrawals

Patients who choose to withdraw from the study may do so at any time without any negative consequences to their medical care.

Data collected up to the point of withdrawal will be used for analytical purposes unless the patient explicitly requests otherwise. Confidentiality and current data protection regulations will be always respected.

5.5. Study Termination

The study will conclude once follow-up of all enrolled patients has been completed and the required sample size for statistical analysis has been achieved.

Likewise, the study may be terminated early by decision of the ethics committee or the principal investigators if unforeseen risks are identified or if insurmountable difficulties in conducting the study arise.

5.6. Sample size

The sample size was estimated using the TwoSampleMean.NIS function from the **TrialSize** package of the statistical software R v.4.4.0. The expected mean difference between the groups in the ZCQ clinical severity subscale is 0.51 with a standard deviation of 0.57. With a non-inferiority margin set at 0.75 (minimal clinically important difference), a one-sided α of 0.05, and a β of 0.20, we estimate that a sample size of 20 patients would demonstrate non-inferiority with a power of 80%. Finally, based also on similar previous studies and considering a dropout rate of 20%, we decided to assume a total N of 24 patients to justify a sample size capable of meeting the general study objectives. (20,21)

6. Experimental design

6.1. Study design and work plan

A single-blind, randomized, controlled non-inferiority clinical trial will be conducted to compare the effectiveness of total osseous decompression of the lumbar canal until normalization of epidural pressure versus open laminectomy in patients with symptomatic lumbar spinal stenosis.

The study will not involve participation from the medical industry, and the research protocol will be registered on ClinicalTrials.gov.

The indication for surgical intervention will be made by a single neurosurgeon from the San Carlos Clinical Hospital, based on clinical scales and imaging studies as outlined in the inclusion criteria. After signing the informed consent form (Annex 2) and being included on the surgical waiting list, patients will be randomized 1:1 using a simple randomization method implemented through SPSS software. Baseline evaluations will include various clinical scales (ZCQ, Numeric Pain Rating Scale [NPRS], Oswestry Disability Index [ODI], and Japanese Orthopedic Association Back Pain Evaluation Questionnaire [JOABPEQ]). The patient will remain blinded to their assigned surgical intervention.

Study interventions (Figure 1):

- **Non–Pressure-Guided Laminectomy (NPGL):** Open laminectomy with total decompression of the posterior elements. This is defined as the classical technique, in which, after muscle dissection, a Codman microsensor (Integra LifeSciences) will be inserted into the epidural space under direct visualization. Careful dissection of the ligamentum flavum below the right hemilamina will be performed to obtain the patient's baseline epidural pressure (Figure 2). The sensor will then

be removed, and resection of the spinous process, supraspinous and interspinous ligaments, hemilaminae, and ligamentum flavum will be carried out bilaterally until proper decompression of the thecal sac is visualized.

- **Pressure-Guided Laminectomy (PGL):** After muscle dissection, the Codman microsensor will be inserted into the lower epidural space as described above. The patient's baseline epidural pressure will be recorded, and osseous decompression will begin following the "unilateral laminotomy for bilateral decompression" technique from the left side, continuing until epidural pressure decreases to 10 mmHg—previously established as a median non-pathological value (22,23).

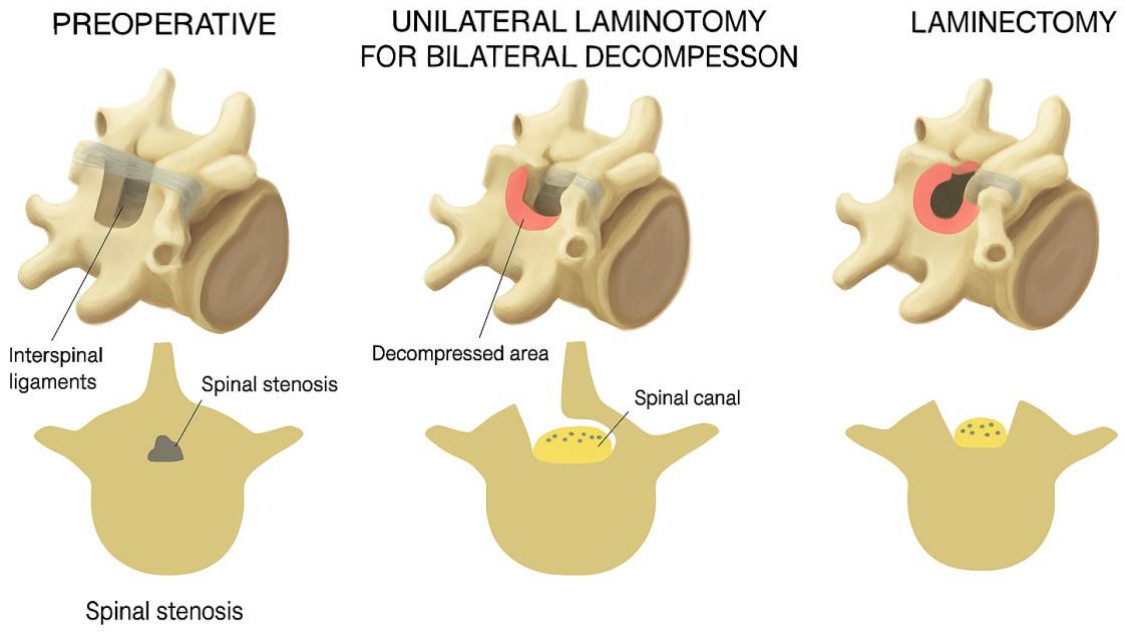


Figura 1. Schematic of the osseous decompression to be performed during surgical interventions (adapted figure). (24)

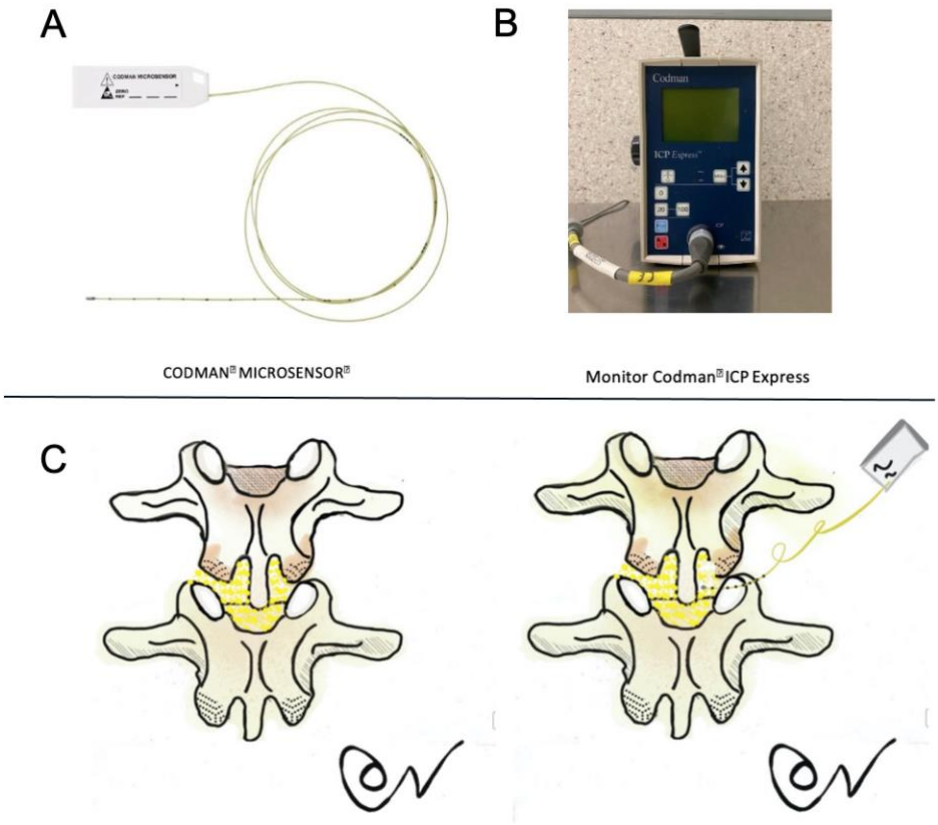


Figura 2. A. Codman Microsensor. B. Codman ICP Express Monitor. C. Technique for inserting the pressure catheter into the epidural space at the stenotic level.

The CODMAN MICROSENSOR pressure catheter (Integra LifeSciences) is a transducer with a micro-strain gauge at its distal end that records pressure changes in a medium. At the proximal end, it has an electrical connector that must be linked to the ICP-EXPRESS monitor. This sensor model was chosen due to its availability in the operating room and its prior use in published scientific studies. (11)

All procedures will be performed by a single neurosurgeon from the San Carlos Clinical Hospital. Patients will be evaluated two weeks postoperatively, during which clinical scales will be applied, and the surgical wound will be assessed. Follow-up will continue at 3 and 6 months via telephone, and at 12 months in person to reassess clinical outcomes.

Additionally, a follow-up lumbar MRI will be performed 3 months after surgery to evaluate the degree of decompression achieved.

6.2. Data collection and information sources

Sociodemographic data and clinical outcome variables will be collected during the preoperative consultation and during follow-up visits at 1, 3, and 6 months, as well as at one-year post-surgery. Imaging data will be obtained from the patient's preoperative (baseline) lumbar spine MRI and from a follow-up MRI performed three months after the surgical procedure. T2-weighted axial sequences will be used to assess the degree of osseous decompression achieved.

6.3. Variables

6.3.1. Outcome variables

- Primary outcome: ZCQ – Symptom Severity Subscale (Annex 4): consists of 7 items assessing symptom severity over the past month using a 5-point numerical scale, where 5 indicates greater severity. The final score is calculated as the mean of all item scores. (28–33)
- Secondary outcomes:
    - ZCQ – Physical Function Subscale (Annex 4): consists of 5 items evaluating functional impairment over the past month on a 4-point scale, where 4 indicates greater disability. The mean score of the items is used as the result. (28,31,33–35)
    - ZCQ – Patient Satisfaction Subscale (Annex 4): consists of 5 items categorized into 4 levels (from very satisfied to very dissatisfied). It evaluates overall outcome, pain relief, walking capacity, ability to work, perform household or gardening tasks, strength, and balance. This subscale will be applied at 6 and 12 months postoperatively. (28,31,33)
    - NPRS (Annex 5): The Numeric Pain Rating Scale is an 11-point scale in which patients rate their pain from 0 to 10, with 0 (on the left) representing "no pain" and 10 (on the right) representing "worst imaginable pain." It will assess both lower limb symptoms (NPRS lower limbs) and low back and/or gluteal pain (NPRS back or gluteal region). (36,37)
    - ODI (Annex 6): The Oswestry Disability Index assesses pain-related disability across 10 items; each scored from 0 (normal) to 5 (severely affected). The final score is calculated as the sum of item scores divided by the total possible score and multiplied by 100. Disability is classified as: mild (0–20%), moderate (21–40%), severe (41–60%), crippled (61–80%), and bed-bound or symptom exaggeration (>80%). (30,38–40)
    - JOABPEQ (Annex 7): The Japanese Orthopedic Association Back Pain Evaluation Questionnaire includes five domains: pain-related disorders, lumbar dysfunction, gait disturbance, impairment of

social life, and psychological disorders. Scores range from 0 to 100, with higher scores indicating better health status. (2,41)
    - Surgical complications.
    - Reoperation.

6.3.2. Variables of interest

- Sociodemographic:
    - Age.
    - Gender.
    - Marital status.
    - Social risk factor (defined as poor family support or undergoing disability benefit procedures)

- Clinical:
    - Duration of symptoms (in months).
    - Pain location (lumbar, lower limbs, or both).
    - Predominant pain type (axial or appendicular).
    - Smoking history.
    - Overweight (BMI > 25).
    - Opioid dosage (expressed in morphine milligram equivalents). (25)

- Imagen:
    - Preoperative MRI:
        - Degree of lumbar canal stenosis according to the Schizas morphological classification (Annex 3). (26)
    - Postoperative MRI:
        - Degree of decompression based on the dural sac cross-sectional area (DSCA) (Figure 3) (24,27)

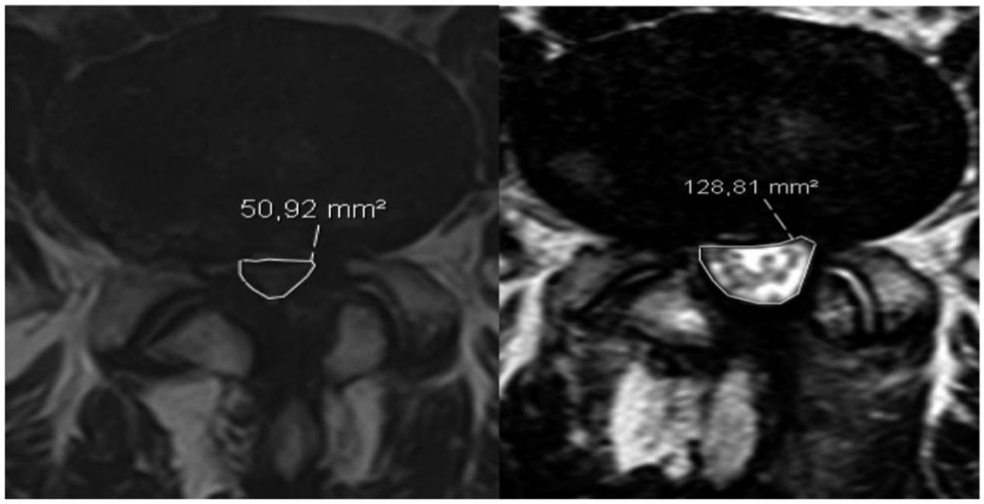


Figure 3. Measurement of the dural sac cross-sectional area before (left) and after decompressive surgery (right) in patients with lumbar spinal stenosis. (9)

6.4. Data management

The database generated by the study will not contain any patient-identifying information; patient identity will remain confidential. Study data will be recorded in a dissociated manner and linked to a code assigned to each patient, so that only the investigator can associate the data with a clinical record. Only the investigators and personnel responsible for ensuring data quality and analysis will have access to participants' clinical documentation.

The study will comply with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, concerning the protection of natural persons with regard to the processing of personal data and the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), as well as with the Spanish Organic Law 3/2018 of 5 December on the Protection of Personal Data and the Guarantee of Digital Rights (LOPDGDD).

The data controller is the San Carlos Clinical Hospital. Its data protection officer is the DPO Committee of the Health Department of the Community of Madrid, which will process the data for the purposes indicated in this document.

Personal data, including health information, will be retained for the duration of the project and for up to three years after its conclusion. Patients may exercise their rights to access and rectify their data, as well as their right to restrict data processing and to request a copy of the data or to have it transferred to a third party.

6.5. Study populations

6.5.1. Per protocol population (PP): Includes all patients who completed all scheduled visits and strictly adhered to the study protocol instructions.

6.5.2. Intention-to-treat population (ITT): Includes all patients who were initially assigned to an intervention group, regardless of whether they deviated from the protocol.

6.6. Data analysis

The demographic and clinical data of the study will be described using descriptive statistical indices. Quantitative variables will be summarized using the mean and standard deviation (SD). For quantitative variables that do not follow a normal

distribution, the median and interquartile range (IQR) will be reported. Qualitative variables will be presented as frequency distributions.

No interim efficacy analysis will be conducted.

The efficacy analysis will be performed using both the Per-Protocol (PP) and Intention-To-Treat (ITT) populations. The safety analysis will be performed exclusively on the ITT population. Data will be analyzed longitudinally, and the primary analysis will focus on differences in effectiveness, measured using the ZCQ scale and other clinical outcome measures, between the two surgical intervention groups. Interactions between treatment and time will also be examined to explore potential temporal variations in the treatment effect.

Non-inferiority analysis will be carried out using linear regression models, applying a one-sided significance level (α) of 0.05 and the non-inferiority margins detailed in Table 1. (20,21,42–46). Multiple non-inferiority hypotheses (one for each clinical scale) will be evaluated. Statistical adjustment for multiplicity will be applied to control the overall type I error rate, progressively narrowing the allowable error margin to maintain the required global error threshold across all comparisons.

Table 1. Non-inferiority margins.

Outcome	Expected difference	Non-inferiority margin
ZCQ (symptom severity)	0,7	0,75
ZCQ (physical function)	0,6	0,6
NRPS back or gluteal	2	1,25
NRPS lower extremity	2	1,5
ODI	10	5
JOABPEQ	20	20

In addition to unadjusted models, all analyses will also be adjusted for potential confounding variables such as age, sex, and comorbidities using multiple linear regression.

The safety analysis will examine the complications that occur during the study period. Their association with the surgical intervention will be analyzed using logistic regression models. For these analyses, a two-sided significance level (α) of 0.05 will be used.

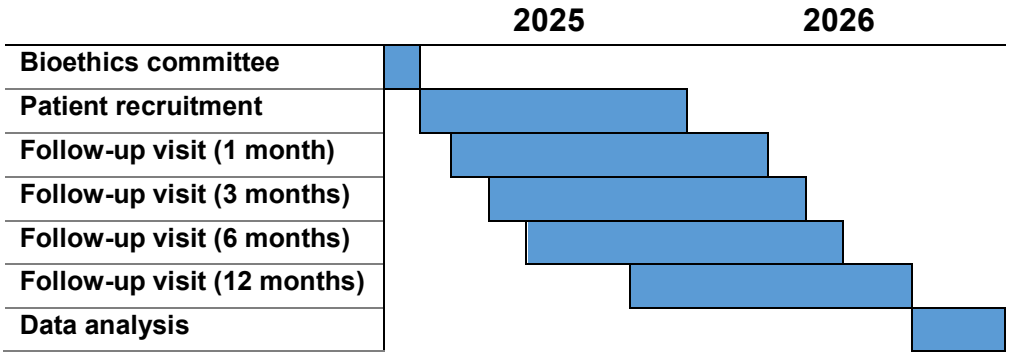
All results will be presented as point estimates with corresponding 95% confidence intervals (CIs). These estimates will be compared against the predefined non-inferiority margins to determine whether non-inferiority can be established. All statistical analyses will be performed using IBM SPSS Statistics version 26 and R version 4.4.1.

6.7. Resources

- Human resources:
  - Neurosurgeon.
  - Neurosurgery Resident Physician.
  - UAMI (Unit for Methodological Support in Research).
- Facilities:
  - Scheduled surgery operating room.
  - Outpatient consultation room equipped with a chair, desk, computer, and examination table.
  - Office with a computer workstation.
- Specialized Equipment:
  - Intracranial pressure monitoring catheter (Codman).
  - Intracranial pressure monitoring device.

6.8. Timeline

The estimated duration of the trial is two years, subdivided into a 12-month patient recruitment period and one year of follow-up.



6.9. Adverse events

It is the responsibility of the investigator to detect and document any event that meets the criteria and definitions of an adverse event (AE). All AEs will be reported in accordance with the guidelines set forth in the *"CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts."*" (47)

6.10. Ethical considerations

The clinical trial will be conducted in accordance with the principles outlined in the Declaration of Helsinki (Annex IV), as well as the current legal regulations in

force in Spain. The study will commence only after obtaining approval from the relevant Clinical Research Ethics Committee (CEIC).

6.11. Dissemination plan

Once the study is completed, the results will be prepared for publication in national or international scientific journals and for presentation at conferences. The principal investigator commits to complying with current Spanish legislation, which mandates the publication of results—whether positive or negative—in scientific journals. The publications will acknowledge the Clinical Research Ethics Committee (CEIC) that approved the study and disclose the source of funding.

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Annex 1. N-CLASS criteria.

Neurogenic claudication caused by lumbar spinal stenosis score (simplified weighted score)	
Age >60 y	4
Positive 30-s extension test	4
Patient reports pain in both legs	3
Patient reports leg pain relieved by sitting	3
Patient reports leg pain decreased by leaning forward or flexing the spine	3
Negative SLR-60 test	2

SLR-60, straight leg raise test is positive if leg pain is produced below 60°.

Annex 2. Informed consent.

INFORMED CONSENT FOR LAMINECTOMY AND EPIDURAL PRESSURE RECORDING

PARTICIPATION IN THE STUDY

You are invited to participate in the study titled: “Non-inferiority of osseous decompression of the lumbar canal until normalization of epidural pressure compared to conventional open laminectomy in patients with symptomatic lumbar canal stenosis.” You have the right to be informed about the procedures to which you will be subjected and the potential complications that may arise. This document aims to explain all these issues. Please read it carefully and consult your Neurosurgeon with any questions that may arise.

We remind you that, for legal reasons, you or your legal representative, if applicable (family member or person with close personal ties), must sign the Informed Consent in order for the surgical procedure to be carried out.

It is important to understand that participation in this study is voluntary. Once you give your consent to be included in the study, you may withdraw it at any time without this affecting your medical care.

Lumbar canal stenosis is a prevalent and disabling cause of lower back and leg pain and is associated with a significant decline in patients' quality of life due to pain and gait impairment. It is defined as narrowing of the spinal canal in the lumbar area, which compresses the spinal nerves traveling to the legs. The diagnosis is established by the presence of characteristic symptoms and confirmed through imaging studies (MRI).

Although multiple theories attempt to explain the effects caused by this disease, the exact mechanism remains unknown. Through this study, our group aims to evaluate the epidural pressure theory by comparing a surgical intervention involving less bone removal to the conventional surgery, with the goal of preventing future mechanical instability of the lumbar spine.

Both surgical procedures are performed under general anesthesia. Access to the affected level will be via a posterior approach to the spine. The procedure involves bone resection at the back of the vertebra to remove excess bone and ligaments and ensure decompression of the dural sac, the structure that covers the lumbar nerves.
By agreeing to participate in the study, you consent to the use of personal clinical and radiological data for analysis, always maintaining the confidentiality of personal data (Annex: confidentiality and data protection).

DESCRIPTION OF STUDY PROCEDURES

By agreeing to participate in this study, you acknowledge that you will be randomized to receive one of the following procedures:

- Open Laminectomy: This consists of the removal of the bony structures of the vertebrae known as spinous processes and laminae, along with the supraspinous and interspinous ligaments and the ligamentum flavum located between the laminae and the membrane covering the nerve roots (dura mater), to decompress the neural structures.
- Unilateral Laminotomy for Bilateral Open Decompression: This involves the resection of the vertebral laminae and ligamentum flavum located between them and the dura mater, with the aim of decompressing the neural structures. The bone resection will be performed from one side only, intending to remove the necessary bone to normalize the pressure on the neural structures. The following structures will be preserved: spinous process, supraspinous and interspinous ligaments, to minimize postoperative segmental instability.

Additionally, the study includes the measurement of epidural pressure at the affected level causing symptoms, before performing the laminectomy and both before and during the laminotomy. This will be done by inserting a pressure microsensor between the ligamentum flavum and the dura mater once the vertebral level has been identified during surgery. The sensor will be removed after pressure measurement in the laminectomy and after completing bone decompression in the laminotomy. These steps do not carry significant surgical risk. During the study, you will not know whether bone resection was guided by pressure measurement and may find out once follow-up is complete or if you choose to withdraw from the study.

PREOPERATIVE

Before surgery, you will need to undergo blood tests, a chest X-ray, and an ECG. You will also have a pre-anesthesia assessment and receive preoperative instructions (fasting hours, medication adjustments, etc.).

POSSIBLE RISKS, DISCOMFORTS, AND CONSEQUENCES

After surgery, you may experience pain at the incision site that may last several weeks. You should know that lumbar stenosis is a degenerative spinal process strongly associated with aging, and that surgery will decompress the lumbar nerves but will not restore the spine to its prior condition. Pain relief is expected, but complete resolution is not guaranteed.

After recovering from anesthesia, the patient will be admitted to the general neurosurgery ward or intensive care unit if required. You will then gradually resume walking with assistance. If there are no complications, discharge will occur within 1 to 3 days. You will return after two weeks for wound care follow-up and suture removal if appropriate.

POSSIBLE COMPLICATIONS

You should know that every surgical procedure carries potential complications due to the technique itself and individual factors (diabetes, heart disease, hypertension, anemia, obesity, etc.). These may require additional medical or surgical treatment and, in rare cases, can result in death.

Main complications include:

1. Spinal cord or nerve root injury: May cause paralysis, sensory deficits, or loss of bladder/bowel control, which may be temporary or permanent.
2. Dura mater injury or rupture: Can occur during surgery or epidural pressure catheter insertion. Even with intraoperative repair, a cerebrospinal fluid leak may develop, requiring bed rest for 5 days or a new surgical procedure.
3. Venous thrombosis in the lower limbs: May lead to leg swelling and, rarely, pulmonary embolism, which can be fatal.
4. Bleeding: May be superficial or deep and occasionally require surgical evacuation.
5. Surgical wound infection: May be superficial or deep and may require reoperation. Can also lead to cerebrospinal fluid infection (meningitis), requiring long-term antibiotics.

ALTERNATIVE TREATMENTS

Alternatives include conventional open laminectomy or continuation of medical treatment: analgesics, anti-inflammatories, lumbosacral orthosis, epidural injections, and rehabilitation.

BENEFITS

It is possible that none of the surgical interventions will improve symptoms. When improvement occurs, it usually lasts up to 4 years post-surgery. The new surgical technique aims to achieve similar clinical improvement with less bone resection, potentially reducing future spinal instability. Your participation will also provide data that may benefit other patients in the future.

PATIENT'S DECLARATION

After receiving this information, the patient or legal representative **HEREBY DECLARES**:

1. Having received clear and precise information from the physician about the personalized risks and alternatives.
2. Being satisfied with the information and having all doubts clarified by the physician.
3. Giving consent to undergo the surgical procedure and participate in the study, allow the recording of described variables, and analysis of obtained results under proper data protection.

4. Understanding the right to revoke consent at any time without reason and without affecting medical care.

Signed in Madrid, on the ____ day of _____20_____

Patient or Legal Representative

Signed in Madrid, on the ____ day of _____20_____

Physician

REVOCATION OF CONSENT

The undersigned patient hereby revokes the consent given to Dr. _____ for the proposed surgical treatment and inclusion in the clinical research study.

This revocation does not result in any prejudice to your medical care.

Signed in Madrid, on the ____ day of _____20_____

Patient or Legal Representative

Signed in Madrid, on the ____ day of _____20_____

Physician

CONFIDENTIALITY AND DATA PROTECTION

All data collected about you and your health during the study will only be used for this purpose. Any future related studies will require prior approval by a Research Ethics Committee.

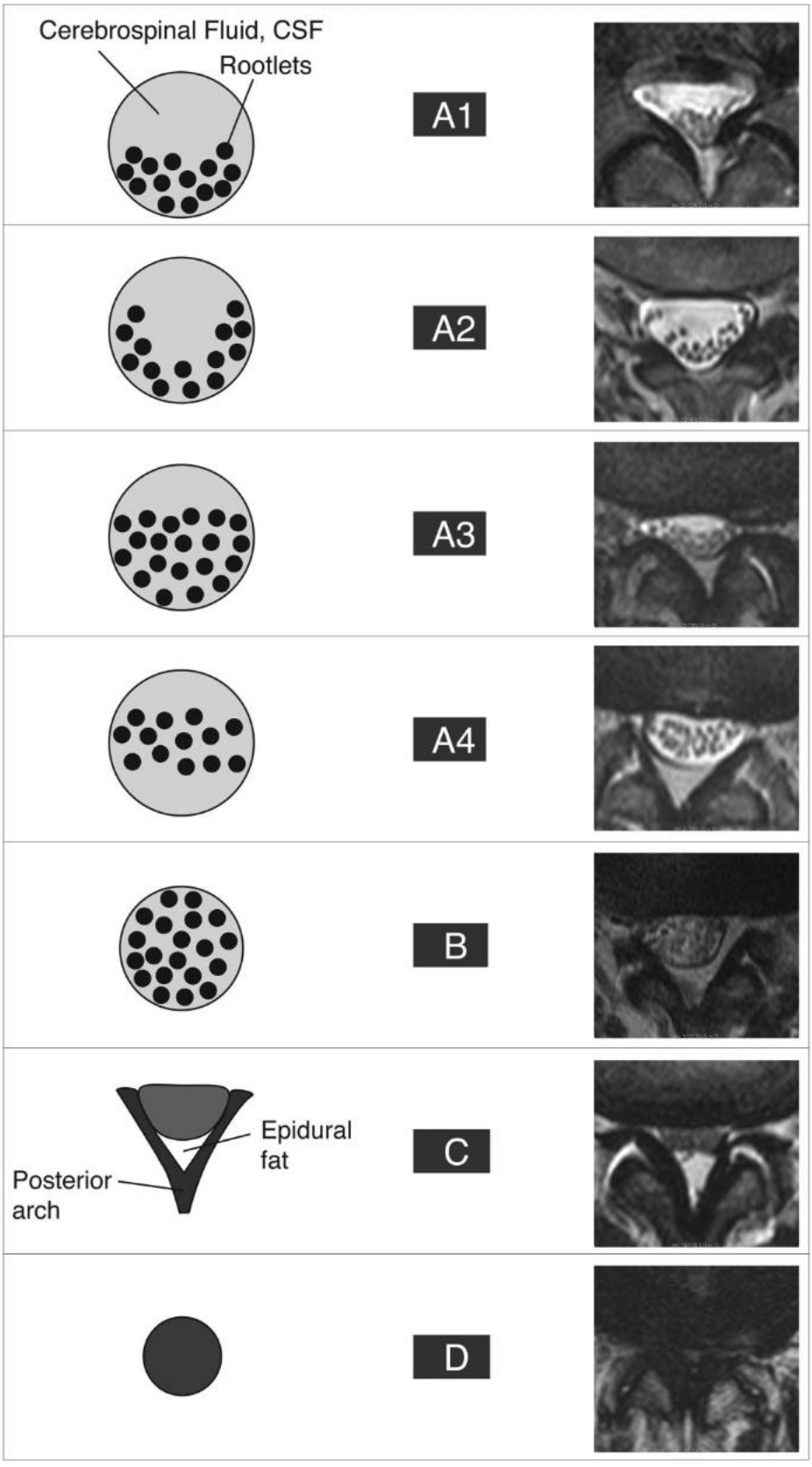
Your data will be treated with strict confidentiality: your name and personal health information will be replaced with a code. Only the principal investigator will have access to the code. Access to the study data (including health information) will be limited to the research team, study monitor, ethics committee members, and competent health authorities to ensure compliance with laws and regulations.

The data controller is Hospital Clínico San Carlos ("HCSC"), which will take all necessary security measures. Your data will be retained until the end of the study and for 25 years thereafter.

According to Organic Law 3/2018 on the Protection of Personal Data and Digital Rights, you may exercise your rights to access, rectify, oppose, or delete your data. You may also restrict processing of incorrect data, request a copy, or request data portability, if applicable. To exercise these rights, contact the principal investigator (NAME, CENTER, TELEPHONE). You may also contact the Data Protection Agency if dissatisfied. More information: https://www.aepd.es/guias/guia-ciudadano.pdf

HCSC Data Protection Officer Contact:
Secretary of the Data Protection Delegate Committee
Calle Melchor Fernández Almagro, 1, 28029 Madrid
Email: protecciondedatos.sanidad@madrid.org

Annex 3. Morphological Classification (Schizas) of Lumbar Spinal Stenosis Based on MRI.



Annex 4. Zurich Claudication Questionnaire (ZCQ) (Spanish adapted version).

Cuestionario de claudicación de Zurich

Durante el último mes, ¿cómo describiría...

1) ... el dolor que ha experimentado, de media, teniendo en cuenta su dolor de espalda, glúteos y piernas?
   1. Ausente
   2. Leve
   3. Moderado
   4. Intenso
   5. Muy intenso
2) ... cuán a menudo ha experimentado dolor en la espalda, los glúteos o las piernas?
   1. Menos de una vez por semana
   2. Como mínimo una vez por semana
   3. Cada día, durante como mínimo unos minutos
   4. Cada día, durante la mayor parte del día
   5. Cada día, a todas horas
3) ... el dolor que ha sentido en la espalda o los glúteos?
   1. Ausente
   2. Leve
   3. Moderado
   4. Intenso
   5. Muy intenso
4) ... el dolor que ha sentido en las piernas o los pies?
   1. Ausente
   2. Leve
   3. Moderado
   4. Intenso
   5. Muy intenso
5) ... el entumecimiento u hormigueo que ha sentido en las piernas o pies?
   1. Ausente
   2. Leve
   3. Moderado
   4. Intenso
   5. Muy intenso
6) ... la debilidad que ha sentido en las piernas o pies?
   1. Ausente
   2. Leve
   3. Moderada
   4. Intensa
   5. Muy intensa
7) ... sus problemas de equilibrio?
   1. No, no he tenido problemas de equilibrio.
   2. Sí, a veces me falta el equilibrio o no me siento con paso firme.
   3. Sí, a menudo me falta el equilibrio o no me siento con paso firme.

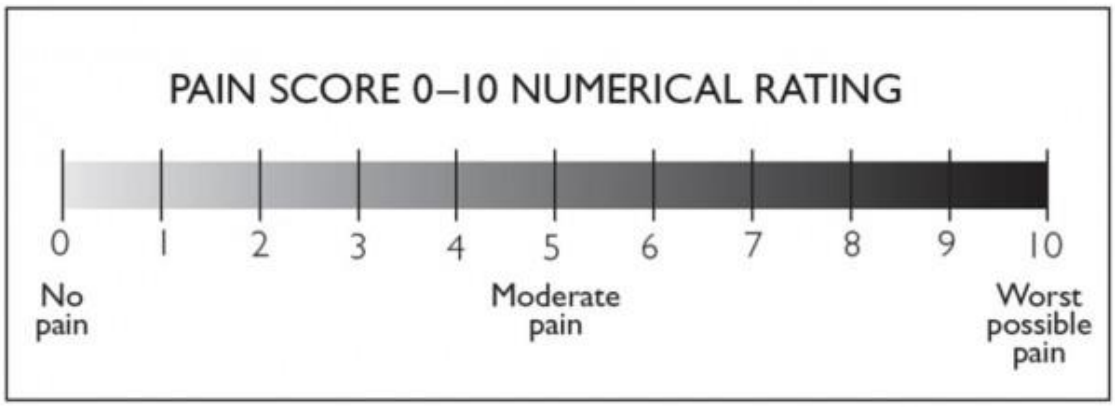
Durante el último mes, en un día normal...

8) ... ¿cuánto ha sido capaz de caminar?
   1. Más de 3 km o una hora
   2. Más de un par de manzanas, pero menos de 3 km o menos de una hora
   3. Más de 15 metros, pero menos de un par de manzanas
   4. Menos de 15 metros
9) ... ¿ha salido a pasear o ha ido a centros comerciales por placer?
   1. Sí, sin problemas
   2. Sí, aunque a veces con dolor
   3. Sí, pero siempre con dolor
   4. No
10) ... ¿ha ido a hacer la compra o de tiendas?
   1. Sí, sin problemas
   2. Sí, aunque a veces con dolor
   3. Sí, pero siempre con dolor
   4. No
11) ... ¿ha caminado por las diferentes habitaciones de su casa o apartamento?
   1. Sí, sin problemas
   2. Sí, aunque a veces con dolor
   3. Sí, pero siempre con dolor
   4. No
12) ... ¿ha caminado desde su dormitorio hasta el baño?
   1. Sí, sin problemas
   2. Sí, aunque a veces con dolor
   3. Sí, pero siempre con dolor
   4. No

¿Cómo está de satisfecho con...

13) ... el resultado global de su operación de espalda?
   1. Muy satisfecho/a
   2. Satisfecho/a
   3. Insatisfecho/a
   4. Muy insatisfecho/a
14) ... el alivio del dolor después de la operación?
   1. Muy satisfecho/a
   2. Satisfecho/a
   3. Insatisfecho/a
   4. Muy insatisfecho/a
15) ... su capacidad de caminar después de la operación?
   1. Muy satisfecho/a
   2. Satisfecho/a
   3. Insatisfecho/a
   4. Muy insatisfecho/a
16) ... su capacidad de realizar su trabajo habitual, tareas domésticas o trabajos de jardinería?
   1. Muy satisfecho/a
   2. Satisfecho/a
   3. Insatisfecho/a
   4. Muy insatisfecho/a
17) ... la fuerza de sus muslos, piernas y pies?
   1. Muy satisfecho/a
   2. Satisfecho/a
   3. Insatisfecho/a
   4. Muy insatisfecho/a
18) ... su equilibrio o la firmeza de su paso?
   1. Muy satisfecho/a
   2. Satisfecho/a
   3. Insatisfecho/a
   4. Muy insatisfecho/a

Annex 5. Numeric Pain Rating Scale (NPRS).



Annex 6. Owestry Disability Index (ODI).

Section 1 – Pain intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- ☐ The pain is very severe at the moment
- ☐ The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc.)

- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it causes extra pain
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but manage most of my personal care
- ☐ I need help every day in most aspects of self-care
- ☐ I do not get dressed, I wash with difficulty and stay in bed

Section 3 – Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed e.g. on a table
- ☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift very light weights
- ☐ I cannot lift or carry anything at all

Section 4 – Walking

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me from walking more than 2 kilometres
- ☐ Pain prevents me from walking more than 1 kilometre
- ☐ Pain prevents me from walking more than 500 metres
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time

Section 5 – Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favourite chair as long as I like
- ☐ Pain prevents me sitting more than one hour
- ☐ Pain prevents me from sitting more than 30 minutes
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6 – Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than 1 hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7 – Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

Section 8 – Sex life (if applicable)*

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9 – Social life

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted by social life to my home
- ☐ I have no social life because of pain

Section 10 – Travelling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from travelling except to receive treatment

Annex 7. Japanese Orthopedic Association Back Pain Evaluation Questionnaire (JOABPEQ).

With regard to your health condition during the last week, please circle the one item number of the answer for the following questions that best applies. If your condition varies depending on the day or the time, circle the item number of your condition at its worst.

Q1-1 To alleviate low back pain, you often change your posture.
1) Yes 2) No
Q1-2 Because of the low back pain, you lie down more often than usual.
1) Yes 2) No
Q1-3 Your lower back is almost always aching.
1) Yes 2) No
Q1-4 Because of the low back pain, you cannot sleep well. (If you take sleeping pills because of the pain, select "No.")
1) No 2) Yes
Q2-1 Because of the low back pain, you sometimes ask someone to help you when you do something.
1) Yes 2) No
Q2-2 Because of the low back pain, you refrain from bending forward or kneeling down.
1) Yes 2) No
Q2-3 Because of the low back pain, you have difficulty in standing up from a chair.
1) Yes 2) No
Q2-4 Because of the low back pain, turning over in bed is difficult.
1) Yes 2) No
Q2-5 Because of the low back pain, you have difficulty putting on socks or stockings.
1) Yes 2) No
Q2-6 Do you have difficulty in any one of the following motions; vending forward, kneeling or stooping?
1) I have great difficulty 3) I have no difficulty
2) I have some difficulty
Q3-1 Because of the low back pain, you walk only short distances.
1) Yes 2) No
Q3-2 Because of the low back pain, you stay seated most of the day.
1) Yes 2) No
Q3-3 Because of the low back pain, you go up the stairs more slowly than usual.
1) Yes 2) No
Q3-4 Do you have difficulty in going up the stairs?
1) I have great difficulty 2) I have some difficulty 3) I have no difficulty
Q3-5 Do you have difficulty in walking more than 15 minutes?
1) I have great difficulty 2) I have some difficulty 3) I have no difficulty

Q4-1 Because of the low back pain, you do not do any routine housework these days.
1) No 2) Yes
Q4-2 Have you been unable to do your work or ordinary activities as well as you would like?
1) I have not been able to do them at all.
2) I have been unable to do them most of the time.
3) I have sometimes been unable to do them.
4) I have been able to do them most of the time.
5) I have always been able to do them.
Q4-3 Has your work routine been hindered because of the pain?
1) Greatly 2) Moderately 3) Slightly (somewhat)
4) Little (minimally) 5) Not at all
Q5-1 Because of the low back pain, you get irritated or get angry at other persons more often than usual.
1) Yes 2) No
Q5-2 How is your present health condition?
1) Poor 2) Fair 3) Good 4) Very good 5) Excellent
Q5-3 Have you been discouraged and depressed?
1) Always 2) Frequently 3) Sometimes 4) Rarely 5) Never
Q5-4 Do you feel exhausted?
1) Always 2) Frequently 3) Sometimes 4) Rarely 5) Never
Q5-5 Have you felt happy?
1) Never 2) Rarely 3) Sometimes 4) Almost always 5) Always
Q5-6 Do you think you are in decent health?
1) Not at all (my health is very poor)
2) Barely (my health is poor)
3) Not very much (my health is average health)
4) Fairly (my health is better than average)
5) Yes (I am healthy)
Q5-7 Do you feel your health will get worse?
1) Very much so 2) A little bit at a time
3) Sometimes yes and sometimes no
4) Not very much 5) Not at all

Measurement:

- Social life function: (‘Q1-2’ × 2 + ‘Q2-4’ × 4 + ‘Q2-5’ × 6 + ‘Q2-6’ × 10 − 22) × 100 ÷ 74
- Mental health: (‘Q1-13’ × 3 + ‘Q2-1’ × 4 + ‘Q2-7’ × 6 + ‘Q2-8’ × 6 + ‘Q2-9’ × 3 + ‘Q2-10’ × 3 + ‘Q2-11’ × 3 − 28) × 100 ÷ 103
- Lumbar function: (‘Q1-4’ × 10 + ‘Q1-5’ × 10 + ‘Q1-6’ × 20 + ‘Q1-8’ × 10 + ‘Q1-9’ × 30 + ‘Q2-3’ × 20 − 100) × 100 ÷ 120
- Walking ability: (‘Q1-10’ × 30 + ‘Q1-12’ × 20 + ‘Q1-14’ × 10 + ‘Q2-2’ × 10 + ‘Q2-4’ × 30 − 100) × 100 ÷ 140
- Low back pain: (‘Q1-1’ × 20 + ‘Q1-3’ × 20 + ‘Q1-7’ × 20 + ‘Q1-11’ × 10 − 70) × 100 ÷ 70