



Original Article

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Received: September 14, 2018

Revised: December 2, 2018

Accepted: December 2, 2018

A Pilot Study of Percutaneous Interlaminar Endoscopic Lumbar Sequestrectomy: A Modern Strategy to Tackle Medically-Refractory Radiculopathies and Restore Spinal Function

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Objective: Angled scopes allow 360° visualization, which makes percutaneous endoscopic techniques (percutaneous endoscopic lumbar discectomy, PELD) particularly attractive for sequestrectomies, which entail the removal of extruded lumbar disc fragments that have migrated caudally or cranially between the ligaments, foramina, and neural structures, while preserving the disc. Although many different PELD techniques are currently available, not all of them are suitable for sequestrectomies; furthermore, long-term follow-up data are unfortunately lacking.

Methods: A pilot study was conducted on a cohort of 270 patients with lumbar radiculopathy undergoing minimally invasive spine surgery (PELD or microdiscectomy), of whom only 7 were eligible for endoscopic interlaminar sequestrectomy with disc preservation. The patients' baseline conditions and clinical outcomes were measured with the Oswestry Disability Index and a visual analogue scale. Long-term follow-up was conducted using satisfaction questionnaires that were based on the MacNab criteria and administered by medical/nursing personnel not involved in their primary surgical management.

Results: EasyGo system was eventually used in 5 PELD cases. No dural tears, infections, or nerve root injuries were recorded in patients undergoing sequestrectomy. Surgical events, including blood loss and overall length of hospital stay, did not differ significantly among the 270 patients. In the group treated with endoscopic sequestrectomy, no recurrences or complications were noted during a follow-up of 3 years, and an excellent degree of satisfaction was reported.

Conclusion: We provide OCEBM (Oxford Centre for Evidence-Based Medicine) level 3 evidence that interlaminar endoscopic sequestrectomy is a tailored and well-tolerated surgical option; nonetheless, a cost-effectiveness analysis assessing the interval until return to working activities and long-term benefits is warranted.

Keywords: Lumbar disc herniation, Endoscopy, Sequestrectomy, Minimally invasive spine surgery, Enhanced recovery after surgery



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INTRODUCTION

Following a technological wave toward minimal invasiveness,

in the last decade the rate of percutaneous minimally invasive spine surgery (MISS) steadily increased, eventually overtaking standard open microsurgical approaches in many instances.

This trend was implemented at any given spinal segments (cervical, thoracic, and lumbar), and for a wide range of pathologies, such as: degenerative stenosis, disc herniations, synovial cysts, traumatic or pathological fractures, and even deformities.¹⁻⁶

The use of the endoscope for lumbar discectomies (percutaneous endoscopic lumbar discectomy, PELD) was fostered by the development of high-resolution endoscopes, optics, and digital cameras which allowed to gain some edges over MISS performed with the aid of microscope or surgical loupes alone. Many different PELD techniques are available nowadays, they include the microendoscopic discectomy, as well as a number of system for endoscopic spine surgery.⁷ They differ with regards to the percutaneous entry point (paraspinal or lateral), and the access to the nucleus pulposus through the interlaminar, posterolateral and transforaminal routes, respectively.

Those techniques were initially proposed for standard lumbar discectomy because of the following advantages: smaller skin incision, less damage to muscular and ligamentous structures, better access to the disc space (even in the axilla), reduced irritation to the nerve root, easier visualization of lateral foramina.

Although many studies showed the good clinical outcomes of the various PELD techniques (and their combination on multilevel lumbar disc disease), concerns were raised about suboptimal or incomplete removal of the disc's annulus/nucleus pulposus, and the long-term results especially in terms of recurrences.⁷⁻¹⁰ Nonetheless, the wider visualization in all axes, favored by the use of angled scopes, makes endoscopic techniques particularly attractive for the removal of the extruded lumbar disc fragment, a maneuver also known as sequestrectomy. This surgical concept was introduced in 1978 by Williams¹¹ to describe the decompression of the nerve root obtained by the exclusive removal of the herniated disc fragment, avoiding any surgical penetration of the disc annulus. The shorter hospital stay and earlier return to work activities, were also advocated in the assessment of its cost-effectiveness.^{12,13} To elucidate the safety and efficacy of this approach compared to other MISS techniques, we report the result of a pilot study on the percutaneous interlaminar endoscopic sequestrectomy with disc preservation, and focus on objective measures of clinical and radiological outcome during a long term follow-up of 3 years.

MATERIALS AND METHODS

Percutaneous endoscopic techniques for lumbar spine surgery were introduced in our Department in 2013, becoming a valuable add to the already existing MISS practice. The highly

selective inclusion criteria for the enrollment in this pilot study were the following ones: young adults (>18 and <60 years of age), complaining of radicular pain, refractory to a 3-month course of conservative management (with analgesics, myorelaxants, and bed rest), with magnetic resonance imaging (MRI) showing all the following specific features: (1) single level, migrated lumbar disc herniation, (2) preserved intervertebral height, (3) nearly intact posterior ligament and annulus fibrosus. Patients with any Modic type endplate changes,¹⁴ spondylolisthesis and other features of spinal instability, defined clinically by mechanical pain or radiologically with segmental movements in flexion-extension X-rays, were not considered eligible for the study. All patients initially assessed for lumbar radiculopathy and scheduled for MISS intervention were screened for participation in this trial. Whenever the neurosurgical team felt to be in equipoise for the sole sequestrectomy, either through standard microsurgical or percutaneous interlaminar endoscopic approach, the patient was automatically invited to a thorough discussion regarding the surgical options, their benefits and related risks, and therefore offered inclusion in the treatment arm of this pilot study. Preoperative and postoperative clinical data of those patients that resulted not eligible or choose not to accept percutaneous interlaminar endoscopic sequestrectomy were kept as control group (Fig. 1).

An informed consent form (previously approved by the local Ethical Committee), detailing the above, was duly signed by all patients at time of enrollment.

The baseline characteristics of each patient included in the study were duly recorded in the data registry, this included demographic information, as well as objective measures of clinical and radiological preoperative conditions. Patients were clinically assessed for radicular and low-back pain using the visual analogue scale (VAS) and for functional status using the Oswestry Disability Index (ODI).

A consensus between neurosurgical and neuroimaging team was reached regarding the radiological aspect of disc herniation and migrated fragment, these were evaluated by axial, sagittal, and coronal T1- and T2-weighted MRI, using the classification of Dora et al.¹⁵

1. Endoscopic System

All procedures were performed with a paramedian posterior approach (2 cm in length, along an imaginary line running 1.5 to 2 cm laterally to the supraspinus ligament (Fig. 2A), depending on the spinal level approached) using a Hopkins 10 cm, Ø2.7 mm, telescopes with 30° angle of view and a Trocar 19 mm (Easy

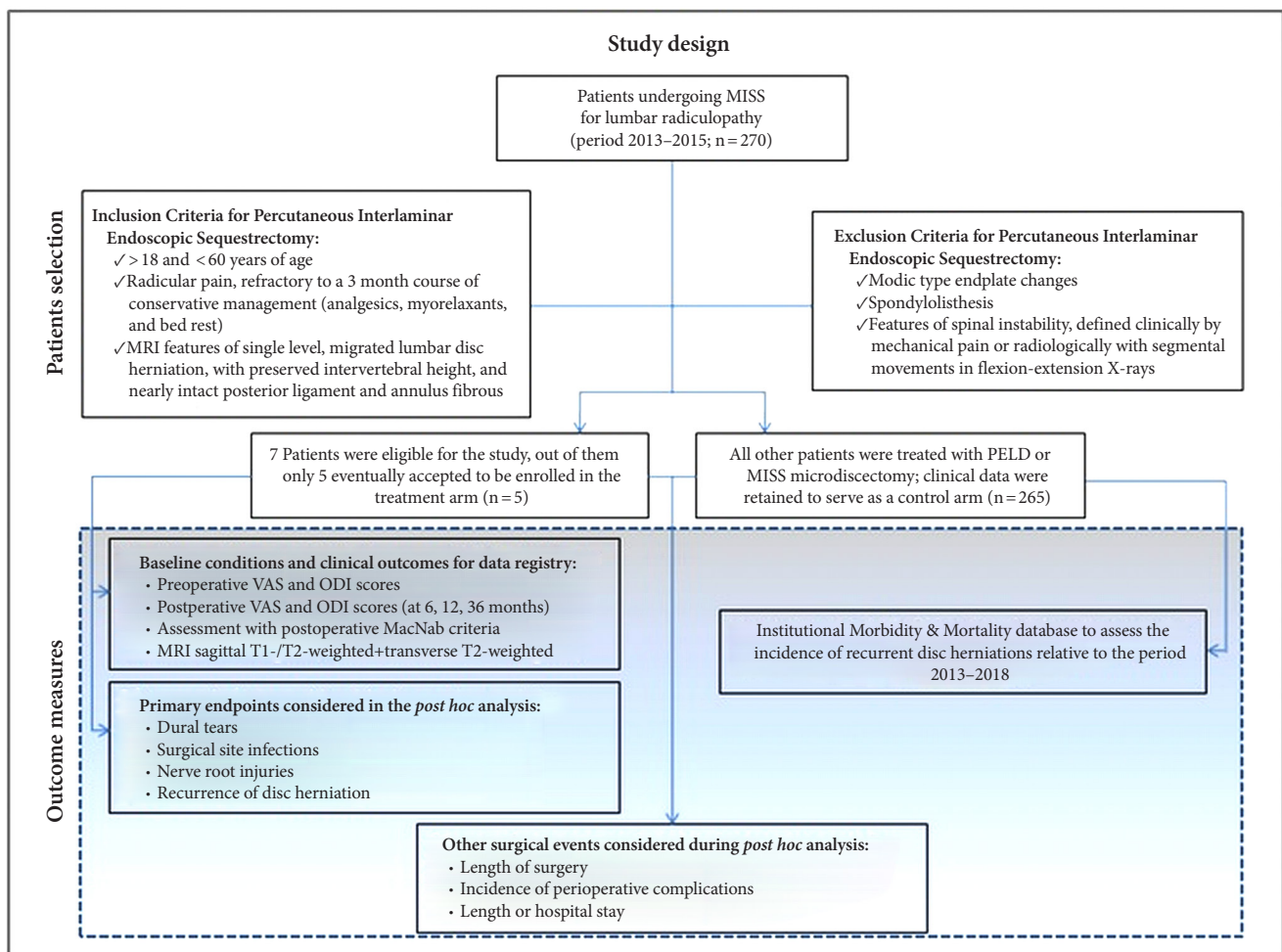


Fig. 1. Study design detailing patients' selection process and assessment of outcome measures. MISS, minimally invasive spine surgery; MRI, magnetic resonance imaging; PELD, percutaneous endoscopic lumbar discectomy; VAS, visual analogue scale; ODI, Oswestry Disability Index.

GO [Gaab-Oertel] ENDOSPINE instrumentation - Karl STORZ GmbH and Co. KG, Tuttlingen, Germany). This system consists of a standard tubular dilator for muscular dilation, a 30° Hopkins rod lens optic, a work sheath of an outer diameter of 19 mm, and an irrigation-suction device, used to keep the surgical site and the optic constantly clean during surgery.

2. Surgical Technique

Upon induction of general anesthesia patients were positioned in a Karlin Frame surgical table, and the surgical site was prepped and draped as usual with povidone iodine and chlorhexidine digluconate. A radiological confirmation of the surgical level was routinely acquired with fluoroscopy, and since none of the patients had allergy to penicillin the prophylactic antibiotic administered intravenously before skin incision was always ce-fazolin (2 g). The muscle fascia was exposed and punctured, the

paraspinal muscles were subsequently smoothly split by the application of dilators, and the endoscopic work sheath was introduced. The endoscopic procedure was performed with bimanual surgical technique and the work sheath fixed to the specific endoscope holder (Fig. 2B). A lateral fluoroscopic check, meant to verify the correct entry angle to access the interlaminar space was obtained before introducing the endoscope, the lamina was then identified and the interlaminar space enlarged with a punch or a diamond drill. The ligamentum flavum was exposed and incised. The dura was subsequently protected with a patty and the thecal sac/nerve root explored and gently mobilized to identify the migrated fragment. The sequestrectomy was performed with grasping forceps, leaving intact the annulus and the disc (Fig. 2C, D). At the end of the procedure the surgical team always verified that the disc fragment removed was congruous with the preoperative imaging (Fig. 3). If necessary, epidural

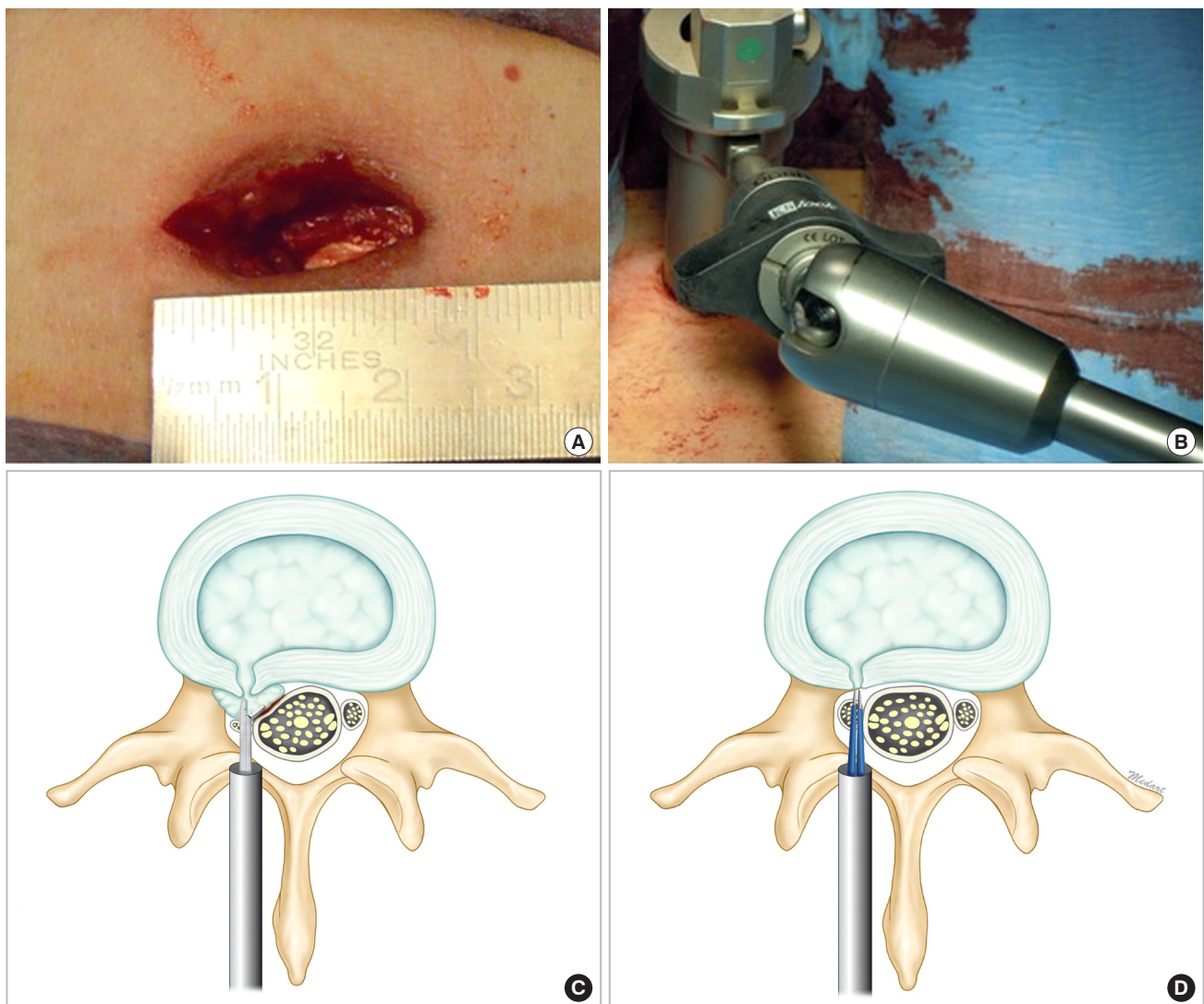


Fig. 2. Stages of percutaneous interlaminar endoscopic sequestrectomy. (A) Limited paraspinous skin incision. (B) Insertion of work sheath fixed to the endoscope holder. (C) Identification of the disc fragment and its removal. (D) Adequate decompression of thecal sac and nerve roots verified at the end of the sequestrectomy.

veins were cauterized with bipolar forceps and divided with microscissors. At the end of the procedure, decompression of the dural sac and the nerve root were meticulously checked, and skin closure performed with 3-0 Nylon.

All sequestrectomies were performed by the same surgical team led by the senior author; the broad experience with MISS techniques including PELD, facilitated the set up and operational phases of this clinical trial. Patients were mobilized from bed within the same operative day, and discharged from hospital with instructions within 24 hours. Risk of venous thromboembolism was assessed and managed with our standard prophylaxis protocol.^{16,17}

3. Outcome Measures

Surgical events including length of surgery, incidence of perioperative complications and length of hospital stay (LOS) were recorded. All patients were followed-up with the same clinical and radiological protocol for at least 3 years after surgery.

The residual degree of disability, the estimated quality of life, and the intensity of residual pain were measured by the use of the VAS at 6, 12, and 36 months postoperatively and ODI (reported only at the last available follow-up). During this period patients received a series of phone calls and attended clinical assessments in our outpatient clinic with repeated administration of satisfaction questionnaires relying on MacNab criteria¹⁸ by medical and nursing personnel not involved in their primary

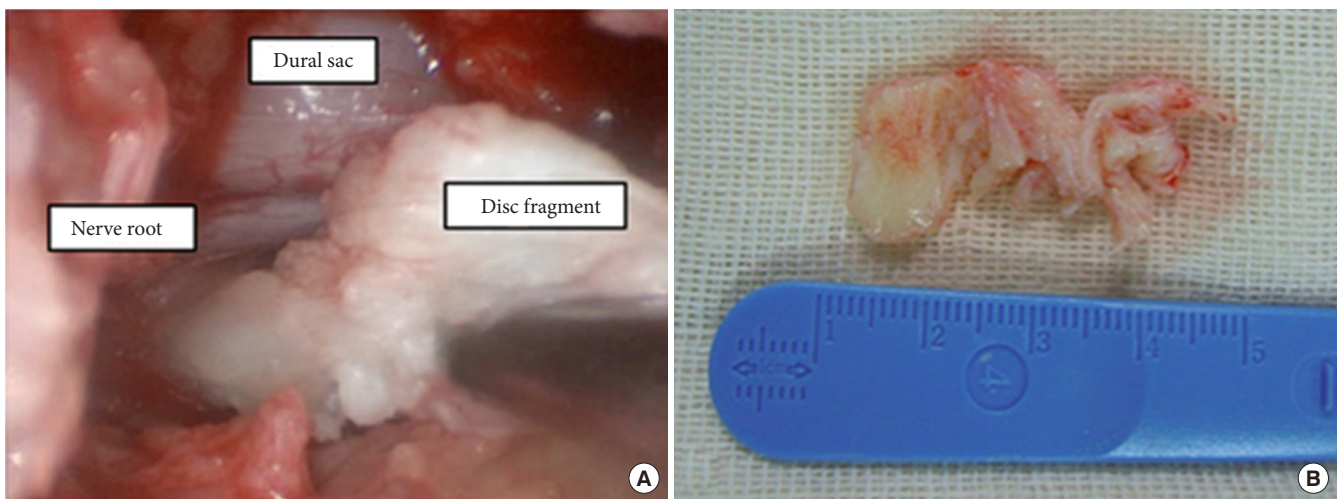


Fig. 3. Removal of extruded fragment and decompression of neural elements. (A) The migrated fragment is completely exposed, carefully mobilized and removed *en bloc* with grasping forceps. (B) Disc fragment removed *en bloc*, confirming that its size results congruous with preoperative imaging.

surgical management. Additionally, all patients underwent postoperative lumbar MRI with a protocol including the acquisition of sagittal T1- and T2-weighted and transverse T2-weighted images.

4. Search Strategy and Criteria for Literature Review

A thorough and systematic literature search was carried out using MEDLINE and Embase databases for studies published in peer-reviewed journals on endoscopic lumbar sequestrectomy. A search was carried out using the following Boolean search criteria ([endoscopy], [lumbar], and [sequestrectomy or sequesterectomy or fragmentectomy]). The resulting studies were then analysed. Finally, the bibliographies of all selected studies were hand-searched for any study not picked up by the original search.

RESULTS

This trial ran for a total of 14 months (December 2013 to January 2015). Among a cohort of 270 patients referred to our Department for radiculopathy due to lumbar disc herniations and considered for MISS, 7 met the abovementioned inclusion criteria. Two out of 7 patients opted for traditional microscopic approach, while the remaining 5 patients accepted to be enrolled in the treatment arm of this study and underwent a percutaneous interlaminar endoscopic sequestrectomy. Their mean age was 45.6 years (range, 28–68 years); and the herniated disc fragment was localized either at the L5/S1 level (3 cases), or L3–4 level (2 cases). The main presenting symptom was a recent on-

set of radicular pain (usually a 4 months' history), whose territory of distribution matched the L4 or S1 dermatomes. Neurological examination resulted within normal limits in all cases but two, in which anterior tibialis muscle (ATM) weakness (Grade 4/5, Medical Research Council scale for muscle strength) was observed on clinical examination. All patients denied red flags for cauda equina syndrome.

All surgical procedures in the treatment arm were uneventful (average length of procedure: 67 minutes, average blood loss: 155 mL), no wound infections occurred in the postoperative period. As planned, all patients were allowed to stand-up and walk on the same operative day and discharged home the day after (total LOS, 2 days). The total number of surgical events considered for both treatment and control arms, including length of surgery, blood loss, and overall LOS did not differ significantly among the 270 patients. In the control group, a total of 12 dural tears were recorded, resulting in a 4.5% incidence; whereas the rate of surgical site infections resulted 3%, specifically 6 cases occurred following MISS microdiscectomy and 2 cases following PELD. Noteworthy, an audit on the morbidity and mortality database of our Department revealed that the incidence of recurrent disc herniation was 4.6% for the total number of cases operated during the period 2013–2018.

In the sequestrectomy group, the average preoperative VAS score was 8.5 (range, 7.8–9.1) for radicular pain and 3.2 (range, 2.6–3.8) for low-back pain. At the follow-up, the VAS score for radicular pain remarkably decreased reaching 2.1 (range, 1.6–2.5) at 6 months, 1.1 (range, 0.8–1.4) at 1 year, and 0.5 (range,

Table 1. Preoperative and postoperative VAS scores

Patient No.	VAS radicular pain				VAS low back pain			
	Preop	6-Month postop	1-Year postop	3-Year postop	Preop	6-Month postop	1-Year postop	3-Year postop
1	9.1	2.5	1.4	0.5	3.5	1.2	0.8	0.3
2	7.8	1.6	1.2	0.4	2.8	0.8	0.4	0.2
3	7.9	1.9	1.1	0.5	2.6	1.1	0.8	0.6
4	8.6	2.2	1.1	0.8	3.8	1.9	0.9	0.5
5	8.9	2.1	0.8	0.3	3.4	1.8	0.9	0.5
Average	8.5	2.1	1.1	0.5	3.2	1.4	0.8	0.4

VAS, visual analogue scale; preop, preoperative; postop, postoperative.

Table 2. Preoperative and postoperative Oswestry Disability Index

Patient No.	Preoperative, score (%)	Long-term postoperative, score (%)
1	34/50 (68)	5/50 (10)
2	32/50 (64)	5/50 (10)
3	30/50 (60)	6/50 (12)
4	33/50 (66)	6/50 (12)
5	34/50 (68)	5/50 (10)
Average	33/50 (65)	5/50 (11)

0.3–0.8) at 3 years; whereas the VAS for low-back pain were reported as follows: 1.4 (range, 0.8–1.9) at 6 months, 0.8 (range, 0.4–0.9) at 1 year, and 0.4 (range, 0.2–0.6) at 3 years (Table 1). The mean preoperative ODI was 33 of 50, 65% (range, 30–34 of 50, 60%–68%), while the mean postoperative ODI at last follow-up (at least 3 years; range, 36 to 51 months) was 5 of 50, 11% (range, 5–6 of 50, 10%–12%) (Table 2).

Both patients with ATM weakness recovered in 2 months, after an intensive rehabilitation period; one patient reported episodes of lumbar or sciatic pain, although significantly reduced compared to before sequestrectomy.

The mean time to return to work was 2.6 months. All patients returned to their previous occupation.

The MRI performed postoperatively ruled out residual or recurrent disc herniation in all cases but one, showing persistence of a small disc fragment, without significant conflict with corresponding nerve root. Of note, this small fragment did not prevent the complete resolution of the clinical symptoms.

Using the MacNab Criteria, at 1 year postoperatively, 4 patients were considered in excellent conditions (grade 3), while one patient in good conditions (grade 2). At the last follow-up available (range, 36–51 months), all patients denied radicular

symptomatology and confirmed to be able to carry out their daily living and working activities without pain medication.

DISCUSSION

Although neurosurgeons are nowadays facing pressing requests for minimally invasive surgery, conventional microsurgical discectomy still remains a widespread option for treating herniated intervertebral disc. It is well known that the downsides of open approaches include extensive retraction and dissection of paraspinal muscles, larger wounds and bone resection. These disadvantages eventually result in slightly longer operative time, blood loss and LOS.

In standard microsurgical lumbar discectomy as described by Caspar and colleagues^{19,20} more than 30 years ago, the radicular decompression is obtained by the removal of the herniated disc followed by curettage of the intervertebral space. In 1978, Williams¹¹ in order to decompress the neural structures without entering the disc, described the concept sequestrectomy, which entails only the removal of the migrated disc fragment. The indication for sequestrectomy is very narrow, however this technique is believed to offer significant advantages in terms of minimizing perioperative pain, preserving disc architecture, and protecting against progressive focal disc degeneration.¹³ In most cases the opening in the annulus fibrosus is expected to seal spontaneously and permanently without further herniation, nonetheless the overall rate of disc recurrence following microdiscectomy is reported to range between 1% and 21%, with a risk that appears to increase proportionally to the degree of annular defect, leading some groups to propose in selected cases the use of specific annular closure devices.^{21–26} In turns, the preservation of the healthy central disc structure is considered crucial to avoid reduction in disc height, decreasing the risk of spinal instability and of postoperative back pain. As such, in se-

lected cases, this tailored option can provide superior results than standard microdiscectomy. For instance, young patients who present with the radiological features of preserved intervertebral height, a disc with otherwise little degenerative changes, and nearly intact posterior ligament and annulus fibrosus may be expected to profit from this management option.

Endoscopy has exploded as a successful strategy in various neurosurgical conditions, including spinal surgery.^{21,22} Nonetheless, the pros and cons of this MISS variant are still debated: previous reports on PELD suggested that it can provide results comparable to microsurgical technique, allowing for the resolution of sciatica with less paraspinal musculature trauma and smaller surgical accesses.²³ Bone removal is often minimal, and this reduces the risks of inducing postoperative spinal instability; furthermore most PELD variants are reported to cause less epidural bleeding and therefore epidural scarring.²³ However, the learning curve is steep, and inexperienced surgeons might encounter perioperative complications and require conversion to open approach: this possibility has to be carefully considered when attempting sequestrectomies, given the risk to get lost and struggle in identifying the extruded fragments between the ligaments, foramina and neural structures. Given the lack of a superiority clinical trial, the literature on endoscopic techniques revolves around single centre surgical series indicating that the vast majority of patients were able to return to their previous occupation earlier than those treated with microdiscectomy.²⁴

Given the potential for: (1) a clearer visualization of the migrated disc fragments under the guidance of the endoscope, (2) less damage to the paraspinal muscles and other normal tissues, and (3) a reduced patient morbidity with an early return to work; our clinical study was designed to address the research question on the effectiveness of percutaneous interlaminar endoscopic sequestrectomy. Beside the rationale for this technique, already detailed above, another technical aspect deserves attention: it is well known that annular defect size is associated with recurrent disc herniation,²⁵ therefore the simple removal of the migrated disc fragment without formal discectomy is itself a measure to minimize the annular defects or fissures. In fact, our literature search allowed to identify several articles supporting the use of lumbar microscopic sequestrectomy,^{12,13,27,28} or endoscopic discectomy,^{22,29-32} nonetheless only few authors proposed endoscopic approaches for lumbar sequestrectomies. Of note, some endoscopic spine systems conceived for posterolateral approach to the lumbar disc through psoas muscle splitting allow for a tailored lateral decompression while sparing the patients from risk of postoperative paraspinal muscles wasting, nonetheless

this surgical route prevents surgeons from being able to perform selective foraminotomies and sequestrectomies. Other PELD techniques should therefore be considered whenever those are deemed appropriate, in particular microendoscopic discectomy is more appropriate for dorsal pathologies, while interlaminar endoscopic systems allow for an easier approach to lower lumbar segments. In fact, at L4/L5 and L5/S1 the interlaminar window is large enough to allow optimal visualization of the neural elements and disc material with just a minimal bone removal and very limited resection of the ligamentum flavum. Some other variants though exist: in 2005, Suess et al.³³ described 41 patients affected by soft extraforaminal disc herniation who underwent percutaneous endoscopic discectomy using the “extraforaminal targeted fragmentectomy” technique. They reported a good outcome in 39 on 41 patients, concluding that this procedure is safe and effective in selected patients. In 2012 Hirano et al.²² reported a series of 37 patients affected by migrated lumbar disc herniation, treated by targeted fragmentectomy through interlaminar, extraforaminal and intraforaminal approach. The authors postulated that percutaneous endoscopic interlaminar lumbar discectomy could be considered as safe and alternative procedure to standard approaches in selected cases. In 2013, Kim and Park²¹ reported their experience on a similar approach for disc herniation at L5–S1 and, in order to reduce the rate of recurrence, they proposed the annular sealing after fragmentectomy. Based on their experience, Kim and Park²¹ focused on the relevance of the learning curve and concluded that the endoscopic sequestrectomy with annular sealing may be a useful technique for reducing early recurrence. Finally, on 2013, Jasper et al.³⁰ published a case report on the endoscopic transforaminal removal of the extruded fragment, a technique similar to the one herein described. Similarly to our series, they also reported good results and focused on the potential advantages of this technique, such as the maintained spinal stability and absence or minimal formation of scar tissue.

The greatest novelty of our study is that it confirms the positive repercussions of endoscopic sequestrectomy in terms of early recovery after surgery, and provides a long-term follow-up without cases of recurrence of disc herniation, instability or failed low back pain. These aspects certainly make the case for the cost benefit effectiveness of this technique.³⁴ As stated by Allen and Garfin,³⁵ although the economic advantages of endoscopic spinal approaches are yet to be carefully studied, the existing literature suggests its potential as a cost-effective intervention, provided that improved clinical outcomes are maintained over time. Although the limited number of cases did not allow

us to perform a proper health economics analysis, the good results recorded in terms of VAS and ODI scores, as well as the excellent degree of satisfaction relying on MacNab criteria up to 51 months following surgery support the consideration of this management option among the spectrum of surgical approaches available for sequestered disc fragments. Given the respect of muscle and paraspinal tissues, limited intraoperative blood loss, and the short operative time, besides being relevant for all those young patients with sequestered disc fragments, this approach could be potentially suitable in groups of individuals with special requirements: such as patients with obesity, coagulopathies, or for professional athletes seeking an early return to competitions.³⁴⁻³⁷

Over the years the instrumentation for endoscopic spine surgery evolved, and newer models are nowadays available so that beyond the EasyGo system tested in this trial percutaneous interlaminar endoscopic approaches can be performed with other full-endoscopic surgical systems. In the future the choice will be even broader due to the continuous competition between producing companies: for the end-user this clearly represents a good news since competition is usually helpful in bringing down costs of initial acquisition or renting. Furthermore, those systems certainly seem to represent a good investment for all spine surgeons performing minimally invasive surgery because of their employability in a number of clinical scenarios beyond the one described in this study. In fact, the endoscopic instrumentation coupled with other technological aids for minimal invasiveness (neuronavigation, intraoperative ultrasound, etc.) can be used as a viable complement for spinal dysraphisms, degenerative and neoplastic spinal pathologies, including tethered cord, minimally invasive interbody fusion, and surgery for intradural tumors.³⁸⁻⁴⁰

The major drawback of designing a single centre clinical trial with strict inclusion and exclusion criteria is that such research approach necessarily narrows down the number of potential candidates at time of patient selection. Additionally, if eligible patients prefer not to be enrolled and opt instead for what is considered to be the standard of care, then it is difficult to rule out the influence of a possible selection bias on the results obtained in both the treatment and control arms. As such, we believe that the absence of dural tears in the sequestrectomy group does not mean that this technique is far superior in terms of safety when compared to standard PELD approaches, but is simply due to the small sample considered. On the other hand, if the approach tested in this pilot study represents a tailored surgical option, it is also true that a bigger sample size could be

achieved only by keeping the trial open for longer periods, or by reducing the criteria for long-term follow-up. Noteworthy, the greatest usefulness of the data achieved with this small clinical trial might become evident when calculating the sample size and power of larger multicentre studies with randomization for percutaneous interlaminar endoscopic sequestrectomy versus other PELD approaches.

CONCLUSION

Although our experience is limited, it provides OCEBM Level 3 evidence that percutaneous interlaminar endoscopic sequestrectomy is a safe and effective option for patients with lumbar radiculopathy caused by single level, migrated lumbar disc herniation, with preserved intervertebral height, and nearly intact posterior ligament and annulus fibrosus. Our long-term follow-up suggests that this option may be considered, in carefully selected patients, as a tailored and well tolerated minimally invasive technique for removal of migrated lumbar disc herniations. This surgical procedure allows for an immediate relief of the radiculopathy and seems to prevent recurrences. Given the above, and the additional advantages of a shorter LOS and early return to work activities, a comparative cost-effectiveness analysis on percutaneous interlaminar endoscopic sequestrectomies is warranted to validate these initial findings.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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