European Journal of Musculoskeletal Diseases
ISSN 2038-4106/2024

Original Article

PERCUTANEOUS INTERSPINOUS DEVICES TREATMENT IN PATIENTS AFFECTED BY LUMBAR SPINAL CANAL STENOSIS: A PRELIMINARY STUDY EVALUATING DURAL SAC USING WEIGHT BEARING MRI, BEFORE AND AFTER THE TREATMENT

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ABSTRACT

Lumbar Spinal Canal and Foraminal Stenosis is a widely diffuse pathological condition responsible for neurogenic claudication. Conventional MRI study may underestimate the disease. Percutaneous interspinous devices has been proposed when significant real stenosis occurs. To evaluate the real stenosis rate before and after the treatment in a population of 72/210 patients affected by symptomatic Lumbar Spinal Canal Stenosis and/or Lumbar Spinal Foraminal Stenosis treated with percutaneous Interspinous Process Device were evaluated by weight-bearing MRI using semi-automatic AI analysis. Seventy-two of a population of 210 patients eligible for Interspinous Process Device treatment underwent a Weight-Bearing MRI lumbar study the day before and one month after the surgical procedure. All the patients underwent percutaneous CT/Fluoro-guided Interspinous Process Devices implant. Minimum Clinically Important Difference, the Zurich Claudication Questionnaire and the Oswestry Disability Index score was rated. Fifty-two out of 210 patients (25% of the study population) became eligible for Interspinous Process Device surgery because Lumbar Spinal Canal Stenosis grading increased on weight-bearing MRI images only, as well as occult listhesis, detected in 21/210. Ratio improvement of the dural sac diameter was statistically significant in all the patients treated in the supine position (ratio 2.0, 95% CIs 1.58, 2.41) and standing position (ratio 3.13, 95% CIs 1.89, 4.37). Weight-Bearing -MRI is the best way to depict true dural sac size before and after Interspinous Process Device implants. Post- Interspinous Process Device studies demonstrated a significant increase in the actual dural sac area after the treatment when immediate postoperative follow-up was performed, reaffirming the

Received: 14 November 2023
Accepted: 03 January 2024

ISSN: 2038-4106

effectiveness of Interspinous Process Device in treating Lumbar Spinal Canal Stenosis patients.

KEYWORDS: *Weight-bearing MRI, Spinal Canal Stenosis, Interspinous device, spacer, spine treatment*

INTRODUCTION

Lumbar spinal canal stenosis (LSCS) and lumbar spinal foraminal stenosis (LSFS) are considered one of the main causes of pain, disability, fall and depression in the elderly (1-3). Despite commonly referred as an age-related disease, the term "degenerative" could be considered a misnomer, as a genetic basis has been recently discovered (4); in fact, in LSCS patients, it has been demonstrated a decreased expression of the main anti-oxidant enzyme - named Catalase - in ligamentum flavum and a deficit of Elastine, responsible for abnormal degeneration of the ligaments associated with Amyloid deposits up to 50% of patients and increased Apolipoprotein AI (AApoAI) level in 12% of patients (5-7).

Clinical symptoms of patients with LSCS include low back pain, stiffness, leg paraesthesia/weakness, lower extremity radicular pain and "neurogenic intermittent claudication" (NIC), generally relieved by sitting and/or bending (1, 8).

Radiologic findings of spinal canal stenosis do not always correlate with symptoms; the diagnosis is typically based on accurate clinical history and physical examination. Imaging studies are useful to confirm the diagnosis and target the treatment (9); in this scenario, several radiological classification systems have been proposed for spinal canal stenosis grading, frequently evaluating the size of the dural sac or even the variation in spinal canal diffusivity, evaluating the variability of lumbar cauda equina nerves apparent diffusion coefficient (ADC) (10, 11).

Actually, the most accepted worldwide is the Schizas's classification based on axial T2-weighted magnetic resonance images (MRI) visual evaluation grade of the spinal canal narrowing in 4 progressive degree (from "A" to "D") (12).

Routinely, the grading of the lumbar stenosis is performed with conventional MRI study acquired in supine position, assuming the value of the stenosis remaining similar in orthostatic position; nevertheless, spinal curve and pelvic tilt differ significantly from supine to upright position, as for paravertebral muscle tones and the absence of physiological body weight. Consequently, there's the realistic possibility in changing stenosis grade when the patient is evaluated in the upright position with a Weight-Bearing MRI system (WB-MRI), according to the changes in the spinal canal and related ligaments that have been demonstrated on dynamic MRI studies (2, 13, 14).

Generally, Schizas's grade C and D only are considered suitable for surgery, while conservative treatment is preferred for grade A and B but the clinical evaluation still drove the treatment, probably also because the radiological conventional MRI evaluation is not so efficient. Actually, physical therapy, self-care and medication are the first step to manage the symptoms of spinal canal stenosis prior to any intervention; however, when conservative treatments fail to improve the patient's pain, function and quality of life, interventional therapies can be considered (15).

Interspinous Process Devices (IPD), also known as "spacers", are considered as an alternative, less invasive treatment versus conventional surgery in patients affected by LSCS or LSFS with similar functional results and less intra-operative complication than open surgery (16). The IPD are intended to be introduced (surgically or with a percutaneous approach) between the two adjacent spinous processes at the level of the symptomatic stenosis enlarging the interspinous space, stretching the yellow ligaments and widening - as a consequence- the dural sac area, mimicking the pain-relief position of kyphosis with a forced flexion of the stenotic level (17, 18). Several studies have been performed concerning the efficacy of spacers in enlarging the bony spinal canal area and the foramina on conventional computed tomography (19); however, the analysis of the real changes of the dural sac area immediately after IPD placement in up-right physiological position has never been evaluated.

In this scenario, our objective is to explore the potential for showcasing a potential shift in the grading and severity of LSCS in patients who exhibit symptoms. This change will be demonstrated by comparing conventional MR scans taken in a supine position with those obtained in an upright position using a specialized whole-body WB-MRI scanner. Furthermore, we assessed treatment outcomes by evaluating the actual enlargement of the dural sac area in an upright position for patients diagnosed with LSCS and/or LSFS immediately after a percutaneous spacer implant. To the best of our knowledge, no existing literature has described the evaluation of the genuine impact of IPD on the dural sac size in the upright position.

MATERIALS AND METHODS

Between September 2021 and June 2022, a total of 210 patients, who experienced mild to severe chronic neurogenic claudication, underwent lumbar spine scanning using a conventional 1.5T MRI. Subsequently, all patients diagnosed with LSCS were further assessed and classified according to the Schizas classification.

Patients classified as Schizas grade C and D were subjected to non-contrast CT scans of the lumbar spine, specifically at the level of stenosis. Those with narrowing caused by bony spurs, ossification of the ligamentum flavum, facet joint hypertrophy, extreme contact, or subluxation of adjacent spinous processes were excluded from the study. Additionally, individuals with a history of previous lumbar spine surgery, and those with spondylolysis and spondylolisthesis graded higher than 2 according to the Meyerding classification (18), were also excluded from the study.

For patients with LSCS deemed suitable for treatment, preoperative electromyography of the lower limbs was conducted to confirm the presence of moderate to severe nerve conduction impairment related to the disease.

All eligible patients for treatment underwent a state-of-the-art WB-MRI lumbar study using a 0.25 T scanner (G-scan Brio®, Esaote, Italy) both one day before and one month after the surgical procedure. The imaging protocol included a 2D Sagittal T2 FSE scan in supine and upright position, with an inclination angle of 81° sequences. The quantitative evaluation of LSCS was performed with a semi-automatic software (Q-Spine®, Esaote, Italy), able to automatically segment Vertebral bodies (L1 to S1) and the spinal canal, performing automatic measures (Vertebral Wedging, Listhesis index, Intervertebral Translation, Intervertebral Angles, Vertebral Collapse Index, Section of spinal canal, Canal thickness, Spine curvature and Foramen area) and, above all, providing a comparison environment giving evidence of the differences between supine and weight-bearing exams. Manual adjustment was performed in some cases when unsatisfactory segmentation was assumed by the operators and measurements were reviewed by two different neuroradiologists. Minimal value of cross-sectional area expressed in mm^2 at the treated level of stenosis, as well as at the level above and below were recorded both in conventional and orthostatic positions, corresponding to the narrowest slice of dural sac.

Those patients who met the criteria for LSCS treatment underwent clinical evaluation, where the intensity of pain was assessed using the Zurich Claudication Questionnaire (ZCQ), and their disability level was measured using the Oswestry Disability Index (ODI). These assessments were performed one day before and one month after the treatment.

The treatment's success was determined based on Minimum Clinically Important Difference (MCID), which were defined as follows: a minimum of 0.5-point improvement in ZCQ domains, an absolute ZCQ patient satisfaction score of 2.5 or lower, and at least a 10-point improvement in ODI (20-23). Technical success was defined as correct placement and deployment of IPD, demonstrated with computer tomography (CT), performed immediately after treatment.

Percutaneous IPD implant procedure

Standard informed consent was obtained. All the patients underwent percutaneous, hybrid procedures with CT and Fluoro-guided approach. The patients were positioned prone on the CT table and a combination of local anaesthesia (10ml Lidocaine 2%) in the deep paraspinal muscles and mild intravenous analgesia, and sedation was administered (*Fentanyl* 1–3 μg/kg/hour).

A low-dose preprocedural scan was performed to choose the correct entry-level point. Subsequently, a small (5–10mm) skin incision was made, and the former 6mm muscle dilator was inserted, via a posterolateral approach, into the interspinous space with appropriate positioning confirmed by further low-dose CT scans. The coaxial guidewire was then introduced through the former dilator and then coaxial dilators (incremental 2mm dilation) were placed. Using fluoroscopic guidance, several different-sized probes were then advanced through the dilator into the interspinous space to choose the proper IPD size. Once the adequate IPD size was selected, a PEEK-covered titanium device with wings for obtaining fixation (Q-Fusion®**,** Diametros Medical, Italy) was subsequently deployed into the interspinous space. In the end, dilators and holder were then removed and the skin was sutured. A quick postoperative CT scan was performed immediately at the end of the procedure, to confirm the device position and assess for immediate complications.

Statistical analysis

Statistical evaluation was performed with STATA 15. Descriptive statistics, including population data are presented

as means ± standard deviation (SD) with range in brackets. Clinical results are presented as mean and 95% confidence intervals. For each patient, dural sac diameter was assessed both in supine and in stand-up position (tilt angle 81°), prior and after the interspinous spacer placement.
Ratio was calculated as follow:

$$Ratio = \frac{\text{Dimension}^{i}_{t1}}{\text{Dimension}^{i}_{t0}} (1)$$

Where is the dural sac diameter after surgery is (tl) for a patient i and the dural sac diameter before the surgery is (t0) for a patient i. We rely on a relative measure of dimensional change to assess the improvement after the procedure. Statistical significance was set at $p<0.05$.

Post-op measurement obtained in the up-right position on weight bearing system always demonstrated statistically significant enlargement of the dural sac at the level of implanted ISD. We registered 100% of technical success rate with regular deployment and implant of the device in all the patients. No major complications have been reported in our series.

RESULTS

Out of the total of 210 patients, 82 individuals (39%) were classified as grade C (37/82) or D (45/82) based on the Schizas criteria. Despite undergoing conservative treatment for at least 6 months, this treatment approach was not successful for these patients. As a result, 72 out of the 210 patients were considered eligible for an IPD implant.

Among the eligible patients, there were 49 males and 23 females. The levels selected for the IPD implant were as follows: L2-L3 (N=1), L3-L4 (N=17), L4-L5 (N=47), and L5-S1 (N=7). The majority of patients (N=35) received a device size of 10, followed by size 8 (N=26) and size 12 (N=11).

Radiological evaluation

A total of 210 patients with LSCS or LSFS underwent WB-MRI. This resulted in a significant change in the diagnosis for some patients, with 47 out of 210 showing an increase in the grade of stenosis in the upright position (Fig. 1a-d).

Additionally, 5 out of 210 patients exhibited relevant foraminal stenosis at the L4/L5 (2 patients)

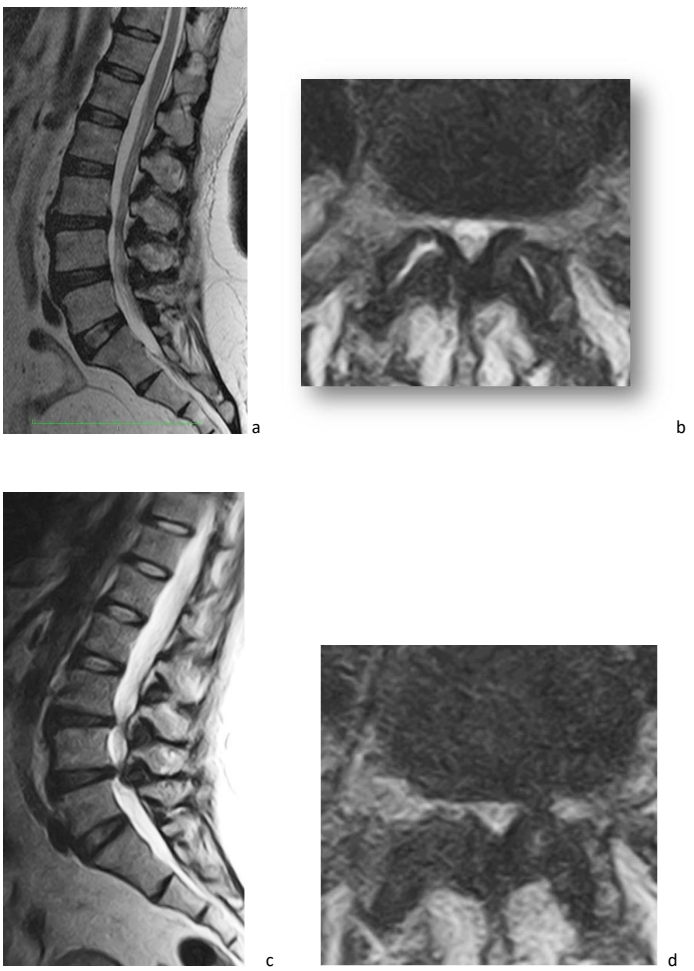


Fig. 1a-d. *A 73yo male affected by positive clinical symptoms suggesting spinal canal stenosis, mild LSCS on conventional imaging and severe increase of stenosis when a weight-bearing MRI study was performed. On conventional supine MRI evaluation, only mild stenosis (grade A LSCS according to Schizas classification) was detected at the level of L4-L5 on sagittal (1a) and axial (1b) T2FSE scan, without any significant deformation of the dural sac nor cauda equina nerve root compression inside. On up-right WBMRI evaluation there is a dramatic increase of the stenosis at L4-L5 level, turning to grade D both on sagittal (1c) and axial (1d) T2FSE scans.*

or L5/S1 (3 patients) level, which was only detected when in the upright position. Consequently, 52 out of 210 patients, representing 25% of the study population, became eligible for treatment solely due to the weight-bearing MRI images. These patients transitioned from grade A/B (no surgery advised) in the supine conventional position to grade C/D (surgery needed) when the weight-bearing MRI scan was performed. Moreover, occult listhesis associated with spinal canal stenosis was detected in 21 out of 210 patients, as a natural consequence of the disease, which was not appreciated on conventional MR imaging (Fig. 2a-d).

The WB-MRI evaluation showed an enlargement of the dural sac after the procedure (fig. 3a-d). Specifically, post-intervention, the dural sac diameter increased both when assessed in the supine position (ratio 2.0, 95% CIs 1.58, 2.41) and standing position (ratio 3.13, 95% CIs 1.89, 4.37), as depicted in Fig. 1.

The estimates at 0° and 81° are not statistically different at conventional $P<0.05$ ($P = 0.06$). In the case of the standing position (orange box plot Table I), two patients displayed a very large relative increase in post-intervention dimensional improvement (Patient 1 ratio = 11.25; Patient 2 ratio 12). Patient 1 showed a dural sac size of 4 mm^2 prior to surgery and 45 mm^2 after the intervention. Patient 2 showed a dural sac diameter of 1 mm^2 before intervention and 12 mm^2 after. Ratio improvement assessed when the patient is standing (81°) without those two extreme cases is lower but still substantial (2.32, 95% CIs 1.83, 2.80).

The patients undergoing treatment showed improvement both in terms of MCID outcomes measured with ZCQ and functionality assessed with ODI; in particular, the average MCID had 1.2-points improvement in ZCQ domains and 2.1 score in absolute ZCQ patient satisfaction score, and the average ODI score improved from 54% mean value to 21%.

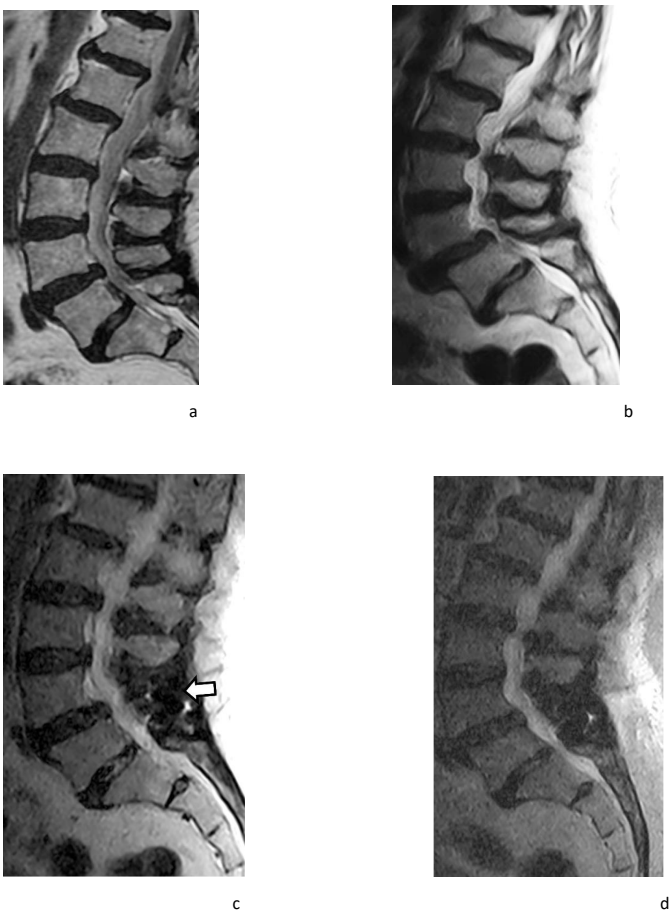


Fig. 2a-d. *A 65yo female affected by LSCS, is evaluated of the dural sac area before and after the treatment with percutaneous Interspinous Device. Before the treatment, severe bulging of yellow ligaments at L4-L5 level (2a) is appreciated on T2FSE up-right weight bearing imaging, responsible for dural sac compression (grade D stenosis). The dural sac diameter size having mean value of 7mm² (2b) according to the automatic segmentation software (Q-spine®). The post-op T2FSE WBMRI imaging performed the very day after the treatment (2c) reveals evident stretching of posterior ligaments, increasing the size of the dural sac, as demonstrated by the dural sac diagram after the treatment (2d), now counting 78mm².*

DISCUSSION

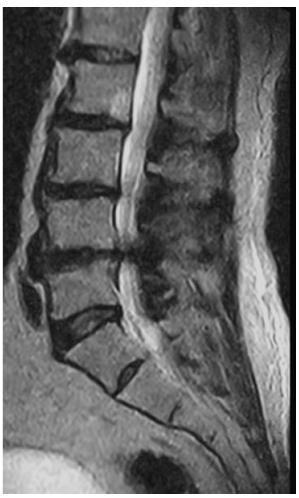
Anthropomorphic measurements of the anteroposterior (AP) size of the spinal canal are not significantly correlated with clinical symptoms in patients clinically diagnosed with LSCS. Therefore, when assessing and treating patients with LSCS, these measures should not be considered on their own (24).

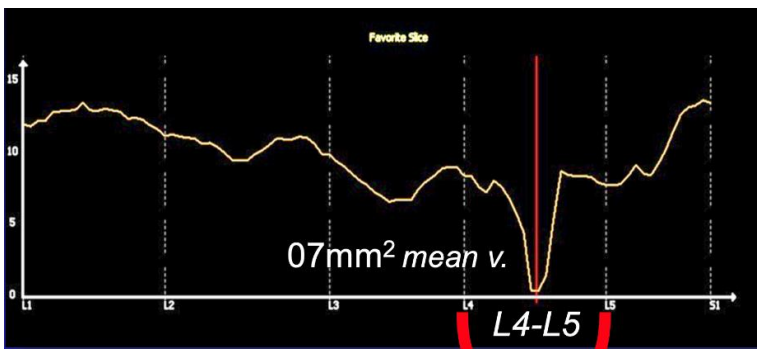
In light of this, our study focused on evaluating the variation in spinal canal diameter expressed as a ratio, rather than relying solely on the absolute spinal canal diameter, to assess improvement after the procedure.

We observed a narrowing of the spinal canal in the standing position compared to the supine position before the IPD implants. This variation explains the development of neurogenic claudication and the worsening of symptoms typically experienced by patients with spinal canal stenosis when axial loads are applied.

Furthermore, several studies have described the dilation of the spinal canal, spinal foramen area, and interspinous space on CT scan images after the introduction of IPD. However, evaluating the dural sac area on CT scans can be challenging due to poor density differentiation between ligament boundaries and the cerebrospinal fluid-filled dural sac, as well as the presence of bone and IPD metallic artifacts. Additionally, despite lumbar spinal canal stenosis being primarily affected by gravitational load stress, all the pre- and post-operative CT studies have been performed in the conventional supine position (19).

Moreover, various studies have reported the expansion of the spinal canal, spinal foramen area, and interspinous space on CT scan images following the introduction of IPD. However, assessing the dural sac area on CT scans can be challenging due to limited density differentiation between ligament boundaries and the cerebrospinal fluid-filled dural





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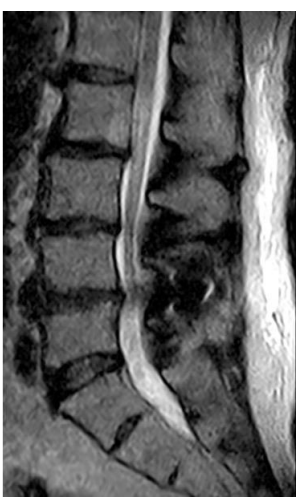
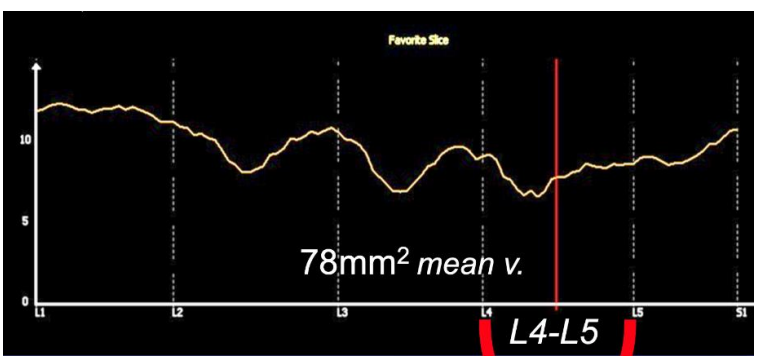




c d

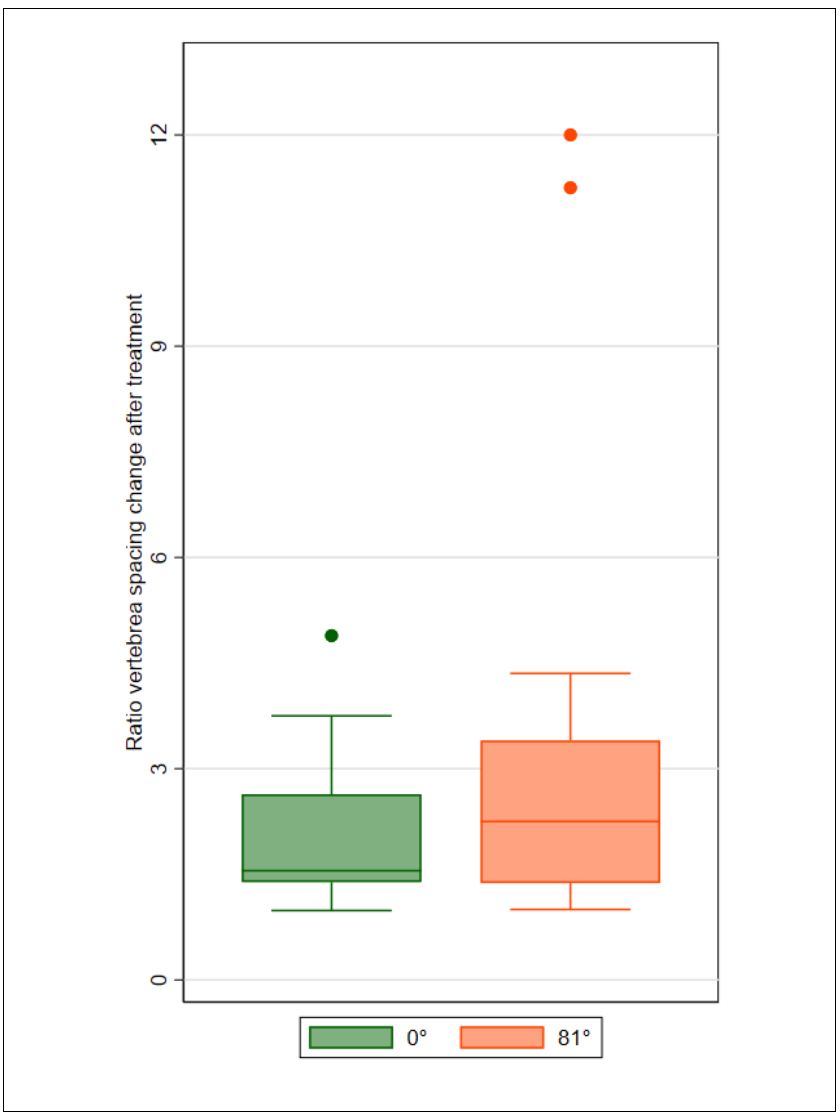
Fig. 3a-d. *Treating occult LSCS + instability in severely symptomatic 77yo female suspected for LSCS and apparent normal spine on conventional supine T2FSE imaging. In supine position, no significant stenosis nor listhesis can be detected on T2FSE sagittal scan (3a). In orthostatic imaging (90degree), significant stenosis at the level of L4-L5 and grade I occult anterolisthesis of L4 is clearly demonstrated, according to the LSCS syndrome. After spacer-fixating device (white arrow in 3c), no spinal canal stenosis nor listhesis can be appreciated both on sagittal supine (3c) and up-right (3d) T2FSE scans.*

sac, as well as the presence of bone and IPD metallic artifacts. Additionally, despite lumbar spinal canal stenosis being primarily affected by gravitational load stress, all the pre- and post-operative CT studies have been conducted in the conventional supine position (19).

A relatively new system called WB-MRI has emerged, offering the evaluation of the spine in a more physiological manner, specifically, in an orthostatic position under the trunk and head load stress of the patient. During WB-MRI, the patient stands in an upright position while a 3D evaluation of the spine is acquired using T2-scan technique. The results are then analyzed with a dedicated software called "Q-spine," which compares all the data (such as dural sac area, foraminal area, grade of listhesis, and curvature of the spine) with the analogous scans acquired in the conventional supine position (25, 26).

Q-spine software is a semi-automatic quantitative analysis tool capable of rapidly calculating spine voxel variations between the supine and orthostatic positions. It provides measurements for the lumbar spine (from L1 to S1) including dural sac and foramina areas (in mm^2), grade of listhesis (in mm), degree of local and global lordosis, and other measurements useful for analyzing the lumbar spine when comparing the conventional supine and upright positions. The 3D voxel

Table I. *Ratio of intervertebral spacing assessed laying (0°) and standing (81°).*



automatic measurement is particularly valuable in accurately evaluating spine changes, as a conventional single 2D measurement on axial or sagittal images may be significantly influenced by various biases, particularly related to different spinal positions during load-stress conditions.

As LSCS is significantly affected by load-stress, it is more logical to evaluate patients in the upright position (27, 28), as failure to do so may lead to the underestimation of lumbar stenosis risk (17-27). Hansen's research clearly demonstrated increased sensitivity and specificity in patients affected by LSCS and/or listhesis when evaluated using a WB-MRI system (28).

In our study, all patients underwent both WB-MRI scans in the upright and conventional supine positions before the IPD treatment. This was done to calculate the actual grade of LSCS and were re-evaluated immediately after the treatment to demonstrate the true extent of dural sac widening following IPD placement. Post-operative measurements, performed in the orthostatic position on WB-MRI, consistently showed a significant widening of the dural sac in comparison to the previous pre-operative scan, both in the supine and upright studies (as shown in Table I). This demonstrates the effectiveness of the IPD mechanism and the rationality in utilizing IPD implants for patients affected by LSCS.

Interestingly, our data indicates that the ratio increased in both supine and standing positions, but it is notably higher in the standing position (ratio of 3.13 vs 2 or 2.32 vs 2 if we remove the two cases with severe stenosis and very high improvement). Moreover, in patients with occult anterolisthesis detected solely on WB-MRI, the application of the IPD, with the included fixating system, resolved the hypermobility of the vertebrae in all unstable patients (as shown in Fig. 2c, d).

This is a key finding of our study, demonstrating the efficacy of IPD implants as devices capable of causing enlargement of the spinal canal that not only persists from the supine to standing position but also increases when axial loads are applied, explaining the clinical improvement in our population.

As a preliminary report, this study is limited by the relatively small number of patients evaluated. However, the statistical analysis was encouraging in adopting WB-MRI criteria to define the disease and evaluate the treatment results. Further case-control studies on a larger population are warranted to validate these findings. Moreover, the clinical follow-up was quite short. Probably a longer follow-up may be advocated to demonstrate clinical results in real-life.

CONCLUSIONS

IPD is a promising treatment option for patients suffering from symptomatic LSCS, offering favourable clinical and radiological outcomes, such as widening the dural sac, meanwhile and reducing the risks commonly associated with major surgical interventions (like decompressive laminectomy).

WB-MRI is currently the only diagnostic tool that allows a more physiological and cost-effective evaluation of the spine in an upright position, providing a true assessment of the dural sac's size before and after surgical treatment, as well as accurately grading LSCS. CT-based measurements typically underestimate the disease due to poor discrimination between ligaments and the dural sac, while conventional X-ray plain films during flexion-extension tend to overestimate the grade of listhesis. As a result, WB-MRI-based measurements should be considered the most accurate for LSCS patients treated with IPD. Furthermore, the Q-Spine software offers additional insights into biomechanical modifications related to posture and pathological conditions by employing 3D models and a comparison environment during weight-bearing evaluations.

Based on our results with WB-MRI, post-IPD studies demonstrated a significant increase in the actual dural sac area after treatment, when immediate post-operative follow-up was performed, reaffirming the effectiveness of IPD in treating LSCS patients.

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