LUMBAR MICRODISCECTOMY WITH INTRASPINE® – A CASE SERIES

MICRODISCECTOMÍA LUMBAR CON INTRASPINE® - SERIE DE CASOS

MICRODISCECTOMIA LOMBAR COM INTRASPINE® - SÉRIE DE CASOS

Chloé Louise Gelder,[1] Martin Drozda,[2] George Spink[2]

1. Queen Elizabeth University Hospital, Glasgow, UK.
2. Hull and East Yorkshire NHS Trust, United Kingdom, UK.

ABSTRACT

Objective: To assess postoperative outcomes following lumbar microdiscectomy (LMD) with and without the use of a dynamic intralaminar device IntraSPINE®. Methods: A non-randomized single-surgeon retrospective analysis. Consecutive elective surgery was performed on patients with lumbar disc disease over a 16-month period. The study group was determined by electronic theatre database. Ninety-two (62 LMD and 30 ILD) of the 95 eligible patients were included in the study, with three being excluded due to incomplete data sets. The pain scores were assessed pre- and postoperatively using a 4-point scale (0 – pain free; 1 – mild; 2- moderate; 3 – severe). Results: The reduction in postoperative leg pain was similar (LMD 1.9 vs. IntraSPINE® 1.8) but the reduction in postoperative back pain was greater in the IntraSPINE® group (LMD 0.5 vs. IntraSPINE® 1.0; p = 0.17). Early recurrence of disc herniation (< 8 months) was lower in the IntraSPINE® group (6.7% vs. 19.4%; p = 0.097). The need for revision surgery was significantly lower in the IntraSPINE® group (p = 0.015). None of the IntraSPINE® recurrences required revision surgery, compared to 97% of the recurrences in the LMD group. Conclusions: This case series raises the possibility that in selected patients, the use of the IntraSPINE® may improve back pain and reduce recurrent disc herniation/revision surgery rates in lumbar microdiscectomy. A prospective randomized trial on the use of the IntraSPINE® should be considered, given the clinical and cost implications of revision surgery. ***Level of Evidence IV; Case series.***

Keywords: Lumbar Vertebrae; Intervertebral Disc Degeneration; Intervertebral Disc Displacement; Diskectomy.

RESUMO

Objetivo: Avaliar os resultados pós-operativos de microdiscectomia lombar (MDL) usando ou não o dispositivo intralaminar dinâmico IntraSPINE®. Métodos: Análise retrospectiva simples não randomizada feita por um único cirurgião de cirurgias eletivas consecutivas em pacientes com hérnia de disco lombar no período de 16 meses. O grupo de estudo foi determinado por um banco de dados eletrônicos de centro cirúrgico. Noventa e dois (62 MDL e 30 com dispositivos intralaminares, ILD) dos 95 pacientes elegíveis foram incluídos na pesquisa, sendo que três foram excluídos porque os dados eram incompletos. Os escores de dor foram avaliados no pré e pós-operatório com uma escala de 4 pontos (sendo 0 – sem dor, 1 – leve, 2 - moderada e 3 –severa). Resultados: A redução da dor nas pernas no pós-operatório foi similar (MDL 1,9 vs. IntraSPINE® 1,8), mas a redução da dor nas costas no pós-operatório foi melhor no grupo IntraSPINE® (MDL 0,5 vs. IntraSPINE® 1,0; p = 0,17). A reincidência precoce de hérnia de disco (< 8 meses) foi menor no grupo IntraSPINE® (6,7% vs. 19,4%; p = 0,097). A necessidade de cirurgia de revisão foi significativamente menor no grupo IntraSPINE® (p= 0,015). Nenhuma das reincidências no grupo com IntraSPINE® exigiu cirurgia de revisão em comparação com 97% das reincidências do grupo MDL. Conclusões: Esta série de casos levanta a possibilidade de que, em pacientes selecionados, o uso de IntraSPINE® pode reduzir a dor nas costas e as taxas de recidiva de hérnia de disco e de cirurgias de revisão na microdiscectomia lombar. Um estudo prospectivo e randomizado do uso do IntraSPINE® deve ser considerado, dadas as implicações clínicas e o custo da cirurgia de revisão. ***Nível de Evidência IV; Série de casos.***

Descritores: *Vértebras Lombares; Degeneração do Disco Intervertebral; Deslocamento do Disco Intervertebral; Discotomia.*

RESUMEN

Objetivo: Evaluar los resultados postoperatorios de la microdiscectomía lumbar (MDL) utilizando o no el dispositivo intralaminar dinámico IntraSPINE®. Métodos Análisis retrospectivo simple y no aleatorio realizado por uno solo cirujano de cirugías electivas consecutivas en pacientes con hernia de disco lumbar durante un período de 16 meses. El grupo de estudios fue determinado por una base de datos electrónicos de centro quirúrgico. Noventa y dos (62 MDL y 30 con dispositivos intralaminares, ILD) de los 95 elegibles fueron incluidos en el estudio, siendo que tres fueron excluidos porque los datos estaban incompletos. Las puntuaciones de dolor se evaluaron antes y después de la operación con una escala de 4 puntos (0: sin dolor, 1: leve, 2: moderado, 3: grave). Resultados: La reducción del dolor postoperatorio de pierna fue similar (MDL 1,9 versus IntraSPINE® 1,8). Sin embargo, la reducción del dolor postoperatorio de la espalda fue mayor en el grupo con IntraSPINE® (MDL 0,5 versus IntraSPINE® 1,0; p = 0,17). La recurrencia temprana de hernia del disco (< 8 meses) fue menor en el grupo IntraSPINE® (6,7% versus 19,4%; p = 0,097). La necesidad de cirugía de revisión fue significativamente menor en el grupo IntraSPINE® (p = 0,015). Ninguna de las recurrencias en el grupo IntraSPINE® requirió cirugía de revisión en comparación con 97% de las recurrencias en el grupo MDL. Conclusiones: Esta serie de casos plantea la posibilidad de que, en pacientes seleccionados, el uso de IntraSPINE® pueda reducir el dolor de espalda y reducir las tasas de recurrencia de hernia de disco y las cirugías de revisión en la microdiscectomía lumbar. Se debe considerar un estudio prospectivo y aleatorizado del uso de IntraSPINE®, dadas las implicaciones clínicas y el costo de la cirugía de revisión. ***Nivel de Evidencia IV; Serie de casos.***

Descriptores: *Vértebras Lumbares; Degeneración del Disco Intervertebral; Desplazamiento del Disco Intervertebral; Discectomía.*

Study Conducted at Hull University Teaching Hospital (HUTH), United Kingdom, UK.
Correspondence: Chloé Louise Gelder. Hull Royal infirmary, Anlaby Road, Hull HU3 2JZ. 07900370082. chloegelder@nhs.net

http://dx.doi.org/10.1590/S1808-185120201903207243

Received on 07/09/2018 accepted on 12/03/2019

INTRODUCTION

The IntraSPINE® is a dynamic intralaminar device produced by Cousin Biotech, and indicated for use in lumbar spine surgery. It is made from medical dimethyl siloxane with a polyethylene terephthalate covering, with the anterior part being designed to perfectly fit the intralaminar space. It is sold in five different sizes (8, 10, 12, 14, 16 mm) and is coated with silicone to prevent fibrosis and adhesions surrounding the spinal structures and the ligamentum flavum. The posterior part is triangular in shape, with a linear cavity designed to distort on vertebral extension.[1] The difference in anterior and posterior compression ratios does not limit the range of movement (ROM).[2] An artificial supraspinatus ligament is supplied for reconstruction in cases of supraspinatus ligament insufficiency, to achieve the correct level of distraction and compression. A unilateral minimally invasive approach is recommended.[3]

As the anterior part of the IntraSPINE® sits more anteriorly in the intralaminar space, the device is closer to the normal segmental axis of instantaneous rotation. Biomechanical studies and didactic tests show that it does not limit posterior extension, but moderately limits flexion, thereby relieving pressure on the disc.[4] Lateral flexion is partially restored, due to the intralaminar action of the device.[3]

The indications of the manufacturer, Cousin Biotech for the use of the IntraSPINE® are "chronic low back pain in black disc with facet-syndrome (preoperative evaluation with dynamic X-Rays and block tests of the facet joints), soft and/or dynamic stenosis and foraminal stenosis after operations for large expelled disc hernias in young patients in order to prevent the collapse of the disc and subsequent chronic lower back pain, and insufficiency of the supra--spinal fibrous complex".[1] Furthermore, it is stated that the device should be used after failure of all conservative methods of treatment, as an alternative to a more invasive surgical procedure and in the first phase of degenerative pathology.[5] The device is designed to be inserted via minimally invasive unilateral posterior approach, either using the device alone or with the artificial ligament.[4]

A search of the current literature on the use of the IntraSPINE® found only data produced by Dr. Giancarlo Guizzardi, the creator of the device. See references and literature search.

METHODS

Literature Search

A literature search was conducted using Ovid Embase, searching on articles published from 1974 to August 15, 2014. The search terms used were: IntraSPINE®, lumbar microdiscectomy, lumbar disk hernia, intervertebral discectomy, microsurgery, lumbar spine, intervertebral disk hernia, lumbar discectomy, lumbar diskectomy, lumbar dis* hernia, intervertebr* discectomy, intervertebr* discectomy, intervertebr* dis* hernia, lumbar spin*, microsurg*, interspinous device and intralaminar device. All titles and abstracts retrieved in the search were screened, to determine the current literature on IntraSPINE® use in patients with lumbar intervertebral disc herniation treated with lumbar microdiscectomy. Literature shown on the Cousin Biotech website was also reviewed.[6]

Data Collection

Ninety-five eligible patients were identified, on whom data was obtained using the electronic theatre database (ORMIS). Ninety-two (62 LMD and 30 ILD) of the 95 eligible patients were included in the series, with three being excluded due to incomplete data sets. Pain scores were assessed pre- and postoperatively using a 4-point scale (0 – pain free; 1 – mild; 2- moderate; 3 – severe).

Clinical Features of the Case Series

All patients in this case series had had lumbar disc nerve root compression with radicular leg pain for more than 8 weeks that was worse than their back pain. As the IntraSPINE® is designed to protect against symptoms from black disc/facet joint disease and further recurrences, the patients selected by the senior surgeon for use of the IntraSPINE® were younger, generally with large prolapses, black disc disease, facet joint disease, and usually very active lifestyles.

Of the 92 patients, 40 were male (43%) and 52 female (57%). Of the 62 LMD patients, 30 were male (48%) and 32 female (52%). In the IntraSPINE® group of 30 patients, 10 were male (33%) and 20 female (67%).

The patients' ages ranged from 18 to 74 years (mean 45 years, mode 41 years, median 44 years and standard deviation 12 years). In the LMD group, patients' ages ranged from 21 to 74 years (mean 47 years, mode 41 years, median 46 years and standard deviation 11 years). In the IntraSPINE® group, the age range was 18 to 71 years old (mean 41 years, mode 48 years, median 40 years and standard deviation 11 years); all values are to the nearest year.

In the LMD group, five of the 62 patients (8%) had had previous lumbar surgery. Of the 30 IntraSPINE® patients, 13 (43%) had had previous lumbar surgery.

Patient Follow-Up and Imaging

The average length of follow-up time was 8 months. Patients with residual or recurrent post op radicular symptoms underwent x-rays to assess the position of the implant, and MRI scans to assess for disc recurrence, scar tissue and infection.

Lumbar Microdiscectomy

The IntraSPINE® device was inserted as per the manufacturer's guidelines; the artificial ligament was only used when the patient's intraspinous ligament was ruptured, and intraoperative steps were taken to ensure that the posterior ligament complex was preserved wherever possible.

Single level microdiscectomies were performed in 82 (89.1%) patients; 23 (76.7%) in the IntraSPINE® group and 59 (95.2%) in the LMD group. Multiple level microdiscectomies were performed in ten (10.9%) patients; seven (23.3%) in the IntraSPINE® group and three (4.8%) in the LMD group. Of the 62 patients in the LMD group, two had a microdiscectomy at the L3/L4 level, two at the L3/L4 and L4/L5 levels, 24 at the L4/L5 level, one at the L4/L5 and L5/S1 levels and 33 at the L5/S1 level. In the IntraSPINE® group of 30 patients, one microdiscetomy was performed at the L3/L4 level, nine at the L4/L5 level, seven at the L4/L5 and L5/S1 levels and 13 at the L5/S1 level.

This procedure was the first lumbar microdiscectomy for 74 of the 92 patients (80.4%); 17 (56.7%) of the IntraSPINE® patient group and 57 (91.9%) in the LMD group. Durotomies occurred in six patients in the LMD group (9.7%). No durotomies occurred in the IntraSPINE® patients.

Data Analysis

A single-surgeon retrospective analysis of patient data was performed.

Statistical Analysis

The statistical significance of leg and back pain reduction was analyzed using an unpaired t-test. Recurrence of disc herniation and the need for revision surgery were analyzed using Fisher's exact test.

RESULTS

Postoperative Back and Leg Pain

Using the 4-point pain scale (0 – pain free; 1 – mild; 2- moderate; 3 – severe), the average pain score was 1.7 for preoperative back pain and 2.7 for preoperative leg pain. The average pain score for preoperative back pain was 1.5 in the LMD group and 2.2 in the IntraSPINE® group. The average preoperative leg pain scores were 2.8 in the LMD group and 2.6 in the IntraSPINE® group.

Postoperative leg pain reduction was similar in both groups; the average reduction in leg pain scores was 1.9 in the LMD group and 1.8 in the IntraSPINE® group. Postoperative back pain reduction was greater in the IntraSPINE® group; the average reduction in back pain scores was 0.5 in the LMD group and 1.0 in the IntraSPINE® group ($p = 0.17$). (Figure 1)

Overall, there was an improvement in back pain after lumbar microdiscectomy in 49 patients (53.3%): 20 patients (66.7%) in the IntraSPINE® group and 29 patients (46.8%) in the LMD group. There was no difference in back pain in 13 patients (14.1%) (seven patients (23.3%) in the IntraSPINE® group and 18 patients (29.0%) in the LMD group) and there was a deterioration in back pain in 18 patients (19.6%) (three patients (10%) in the IntraSPINE® group and 15 patients (24.2%) in the LMD group).

Early Disc Recurrence

Early disc recurrence (< 8 months) was lower in the IntraSPINE® group. Overall, 14 patients had early disc recurrence; two in the IntraSPINE® group and 12 in the LMD group (6.7% vs. 19.4%; p = 0.097). (Figure 2) Nerve root blocks were used to treat the pain caused by early disc recurrence in five of the LMD patients with disc recurrence (four of those had revision surgery); none of the IntraSPINE® patients with disc recurrence required nerve root blocks.

Revision Surgery

Of the 14 patients that had disc recurrence, ten required revision surgery. None of the IntraSPINE® recurrences required revision surgery, compared to 97% of the recurrences in the LMD group (p = 0.015) that did require revision surgery. (Figure 3)

Device Integrity

There have been no cases to date, in this small case series, of the implant becoming infected, moving, or requiring removal.

DISCUSSION

This case series raises the possibility that the use of IntraSPINE®, in selected patients, may improve back pain and reduce recurrent disc herniation/revision surgery rates in lumbar microdiscectomy.

Postoperative Leg and Back Pain Reduction

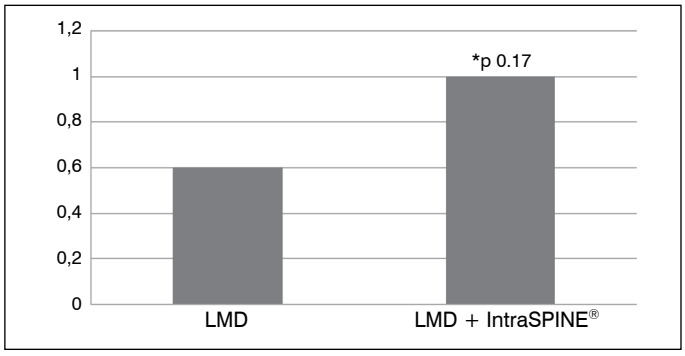

Figure 1. Average postoperative reduction in back pain score. (LMD – Lumbar Microdiscectomy alone. LMD + IntraSPINE® - Lumbar Microdiscectomy with IntraSPINE® insertion).

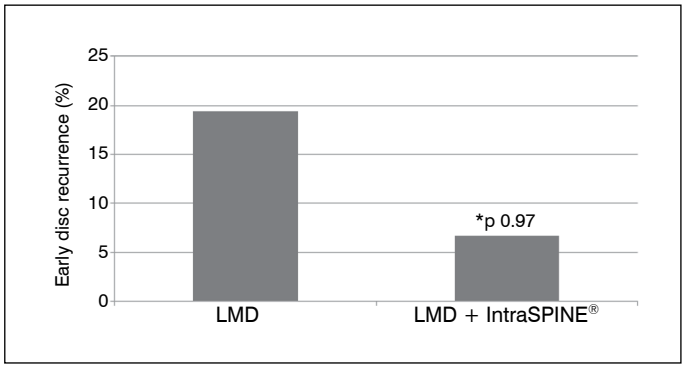

Figure 2. Percentage of early disc herniation recurrence (< 8 months). (LMD – Lumbar Microdiscectomy alone. LMD + IntraSPINE® - Lumbar Microdiscectomy with IntraSPINE® insertion).

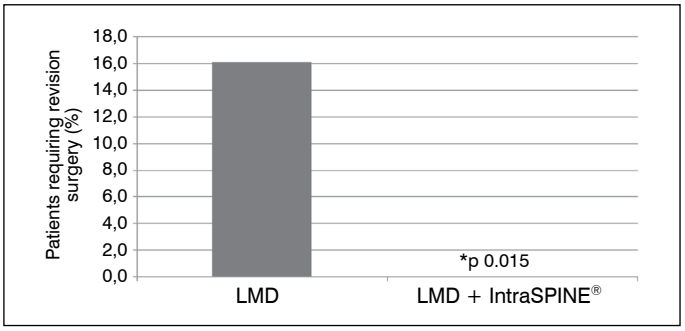

Figure 3. Percentage of patients that required revision surgery. (LMD – Lumbar Microdiscectomy alone. LMD + IntraSPINE® - Lumbar Microdiscectomy with IntraSPINE® insertion).

These results showed a reduction in patients' level of back pain with the use of the IntraSPINE® device, despite it being indicated for the treatment of radicular leg pain; there was an average 1.0-point reduction on the 4-point pain scale (p = 0.17). There was no difference in the level of leg pain reduction between the two groups.

Guizzardi et al.[5] showed a mean reduction in the visual analogue score (VAS) for lower back pain of 8.1 to 1.3, and in the Oswestry Disability Index (ODI) for lower back pain of 33.8 to 12.8, in patients with degenerative discs with facet syndrome; a mean reduction in VAS score of 8.4 to 0.5 and in the ODI of 40.1 to 11.6 in those with large extruding disc herniations, and a mean reduction in VAS score of 8.0 to 1.1 and in the ODI of 36.5 to 11.5 for those with soft stenosis without decompression. Therefore, our findings support those of other studies. The reason for a reduction in back pain is most likely due to a combination of normalization of the center of rotation and offloading of the disc in flexion.[5]

Early Disc Recurrence

Our study demonstrates a reduction in the number of patients with disc recurrence post-IntraSPINE® insertion compared to those with LMD alone (p = 0.097).

Revision Surgery

None of the patients in the IntraSPINE® group with a disc herniation recurrence required revision surgery (p = 0.015). In an Italian multicenter study with 2-year follow up of 84 patients, three of the patients (3.6%) required revision surgery within six months of the original procedure. Of the three patients in this study that required revision surgery two suffered from degenerative disc with facet syndrome, and one suffered from soft stenosis without decompression. In Guizzardi et al.[5] none of the patients with a large extruded disc herniation and use of IntraSPINE® required revision surgery.[5] This is in agreement with the findings of our series, suggesting that one possible clinical indication for the IntraSPINE® device is in patients with large extruded disc herniations.

Revision surgery after disc herniation recurrence was required in ten patients in whom the IntraSPINE® device was not used. This high revision rate is due to the surgeon's preference for a fairly aggressive approach in managing recurrent discs, and the fact that the patients were offered revision surgery at the same time as conservative management. The logistics of alternative conservative treatment with spinal injections was such that at the time of this series, the waiting time for a nerve root block was > 4 months, therefore most patients, when given the choice, opted for surgery.

Responders and Non-responders

A longer follow-up is required, as the characteristics of the IntraSPINE® group may affect recurrence risk rather than the use of the IntraSPINE® per se. There were more females than males in the IntraSPINE® group; this group also had a higher number of patients who had undergone previous lumbar surgery, compared to the LMD group. Of the patients who saw a distinct improvement

in their pain scores (of 2 to 3 points) there were no discernible differences in the patient demographics in comparison to overall group demographics.

CONCLUSION

A prospective randomized trial of IntraSPINE® usage in young patients with large extruded discs undergoing surgery for relief of radicular leg pain should be considered, given the clinical and cost implications of a postoperative reduction in back pain and the need for less revision surgery. This would identify whether the findings of this case series are reproducible, and whether there are any consistent characteristics among patients who respond to the IntraSPINE® device and those who do not.

ACKNOWLEDGEMENTS

Miss Anna Craig-McQuaide (Neurosurgery, Queen Elizabeth University Hospital, Glasgow).

All authors declare no potential conflict of interest related to this article.

CONTRIBUTION OF THE AUTHORS: Each author contributed individually and significantly to the development of the manuscript. CLG: Substantial contribution to the conception or design of the work, or acquisition, analysis or interpretation of the data for the work as well as writing of the work or critical review of its intellectual content. MD: analysis and interpretation of the data for the work as well as critical review of its intellectual content. GS: Substantial contribution to the conception or design of the work, or acquisition, analysis or interpretation of the data for the work as well as writing of the work or critical review of its intellectual content.

REFERENCES

1. Cousin Biotech, IntraSPINE®, France, Cousin Biotech. 2013.
2. Guizzardi G, Morichi R, Mattioli CM, Scaglione V, Ceccarelli M, Amoroso E, et al. Italian Multicentre Study on the use of a new interlaminar prosthesis (IntraSPINE®) in DDD of the Lumbar spine: preliminary report. Deutscher Wirbelsaulenkongress. Congress Centrum Ulm. 2008.
3. Guizzardi G, Petrini P. Interspinous versus Interlaminar devices in DDD: Biomechanics Tests. Deutscher Wirbelsaulenkongress Internationales Congress Center Munchen. 2009.
4. Guizzardi G, Petrini P. Biomechanical consideration on posterior motion preservation systems. Interspinous versus interlaminar devices. Columna. 2011;1(2):31-8.
5. Guizzardi G, Morichi R, Pradella S, Piccardi B, Amoruso E, Ceccarelli M, et al. Not Interspinous, but Interlaminar, Not Decompression Device, but Overload Assistence Device: INTRASpine, a Posterior Motion Preservation Device in Lumbar DDD; Biomechanichs, Indications and Clinical Results (up to 2 Years Follow up). Internacional Society for the advancement of spine surgery. 2011.
6. SUMHIT, Spinal Surgery - Lumbar - IntraSPINE® - Dynamic Interlaminar Device - Cousin Biotech. 2014. [Access in ? 10th April 2015] Available in : <http://www.cousin-biotech.com/en/products-cousin-biotech/spine-wide-range-products-made-of-soft-materials/intraspine-device-interspinous-space-laminar-support>