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TRANSPARS MICROSCOPIC APPROACH FOR THE TREATMENT OF PURELY FORAMINAL HERNIATED LUMBAR DISC: A CLINICAL, RADIOLOGICAL TWO-CENTER STUDY

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Dear Editor,

Thank you for the possibility to resubmit this paper. We have greatly appreciated the reviewers' comments, since those criticisms have given us the opportunity to improve the quality of our article.

Reviewers' comments:

Reviewer #2: This is an interesting study examining outcomes of intraforaminal disc herniation operated via a transpars approach. I have following critics:

1-They have not compared their cases with another approach.

1R-you are right. The aim of this study is to analyze safety and efficacy of the transpars approach alone. The next step will be an anatomical/radiological study comparing different corridors followed by a clinical study

2-The outcome scores would be more reliable if they have used Oswestry disability index instead of Macnab criteria. They could have given leg pain numeric ratings and back pain numeric ratings separately

2R-We discussed on this during the preclinical phase of this study. I agree with you that ODI provides a good measure of disability. Macnab scale is, instead, rough, lacking detailed metrics of symptomatology and cannot be used alone. Therefore, we decided to couple Macnab scale with other outcome measures (drugs intake, working days lost) and with another pain evaluation scale: NRS. In this way we were able to obtain a simple information on outcome (Macnab) and a patient self-evaluation of pain. To date it is not possible to add another scale such as ODI, since the ODI questionnaire cannot be filled in retrospectively.

We have added a brief sentence in the discussion on this limitation.

In this study, all patients had very intense radicular pain prior to surgery. All patients reported preoperative back pain to be negligible, since leg pain was totally predominant. Therefore, we only evaluated leg pain with NRS

3-They have done no discussion on lateral (inter-transverse) approach for foraminal disc herniations.

3R-we have now briefly discussed on this.

Reviewer #3: In this study, the authors report the results of a prospective study of 47 patients that underwent a transpars approach to a far lateral lumbar disc herniation. Length of followup was 12 months. Patients were evaluated with regard to work status, NRS, neurologic status, and medication use pre- and post-operatively. Postoperatively, patients also underwent dynamic xrays looking for instability as well as outcome assessment using McNabb's criteria.

Overall the patients did well, with 93.3% reporting good or excellent outcome. There were no complications and only patient with new detected spondylolisthesis.

The authors conclude that the procedure is safe and effective.

This is a good manuscript that describes a useful technique. There are a few areas that could use improvement however:

1. Page 1, lines 2-3: What were the exclusion criteria? Were any patients excluded?

1R. We have now added in the methods that "Contraindications to surgery were active cardiovascular disease (acute heart insufficiency, recent myocardial infarction, instable coronary syndrome) and other contraindications to general anesthesia (i.e. pneumonia, sepsis etc...). No patients were excluded from this study.

2. Page 1, lines 50-51: I doubt that a twist drill was actually used. Did the authors mean high speed drill?

2R. we have now corrected this.

3. Page 3, lines 9-10: What percentage of patients during this time that had far lateral discs had the procedure or were included in the study?

3R. We have now modified the text adding this information. "These 47 patients represented 5.5% of all patients operated for lumbar herniated disc and 92% of 51 patients with FLDH we observed in that period at the two centers (Table1)." The remaining 4 patients did not meet the inclusion criteria, as they did well with drugs.

4. Page 3, last paragraph: I assume that all patients in the study completed the 12 month follow up period and that none were lost to follow up. If true, this should be stated explicitly

4R. in the "Preoperative clinical and radiological characteristics" subheading we wrote that: "No patients were lost at follow-up."

5. Page 6, line 29-30: Dr Nancy Epstein is female. Please change the pronoun to "her" or change to "this paper"

5R. OK sorry!!!

6. The discussion section is rather lengthy. If it could be shortened that would enhance the paper.

6R. we did it, thank you for your suggestion

7. The level of evidence here is 4. There is no comparison group

7R OK

Transpars Microscopic Approach for the Treatment of Purely Foraminal Herniated Lumbar Disc: A Clinical, Radiological Two-Center Study

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Abstract

Study Design. This is a prospective two center study.

Objective. The aim of this study was to assess the safety and efficacy of treating patients with lumbar foraminal disc herniations via a microscopic transpars approach, with a clinical and radiological follow-up evaluation.

Summary of Background Data. Purely foraminal lumbar disc herniations comprise about 5% of all lumbar herniated intervertebral discs. Operative management can be technically difficult, and the optimum surgical treatment remains controversial.

Methods. From January 2012 to January 2015, 47 patients were prospectively recruited. Patients were followed-up as outpatients at one week after discharge, then at one, six and twelve months.

A clinical multiparametric evaluation of patients including NRS, drugs intake, Macnab criteria and working days lost was used.

Post-operative dynamic X-rays (flexion, extension) were performed in all cases twelve months after surgery.

Results. No surgery-related complications occurred.

Among the 35 patients who were not retired at the time of the study, 29 patients returned to work and to normal daily activities within 60 days after surgery.

Pain evaluation at discharge showed a significant improvement of NRS score, from 8.93 to 1.45 at twelve months. Root palsy significantly improved in all cases already at one month follow-up. Drugs intake analysis showed at six-month follow-up, no patients used steroids, or Opioids, 17 patients used NSAIDs when needed, 29 patients (61.7%) used no drugs for pain relief. No significant variations occurred at twelve month-follow-up.

At twelve-month follow-up, Excellent or good outcome (Following Macnab criteria) were achieved in 36 (76,6%) and 8 (17%) patients, respectively.

There were no cases of spinal instability at twelve-month radiological evaluation.

No recurrence occurred at follow-up.

Conclusions. Transpars microscopic approach is effective and safe for the treatment of FLDH, but larger studies are needed.

Key Words: Foraminal herniated lumbar disc; Microscopic approach; transpars approach; multiparametric evaluation; outcome

Level of Evidence: 3

Keypoints.

-A multiparametric analysis of outcome after Transpars approach for foraminal herniated lumbar disc has been carried out.

-Clinical results show excellent outcome in terms of drugs used for pain relief, working days lost, MacNab criteria, VAS score for pain

-Radiological results at 12 month follow-up show no cases of instability were encountered

-The transpars microscopic approach is a safe and effective method for treating foraminal herniated lumbar disc herniation

Mini Abstract.

This study was undertaken to determine the efficacy and safety of the transpars approach for the treatment of Foraminal herniated lumbar disc (FLDH).

47 Patients were followed-up until twelve months with radiological and clinical multiparametric evaluation.

Transpars microscopic approach is effective and safe for the treatment of FLDH.

Introduction

Purely foraminal lumbar disc herniations (FLDH) comprise about 5% of all lumbar herniated intervertebral discs.^{1,2} Most commonly, FLDH occurs at L3-4, L4-5, or higher levels.

FLDHs are more likely to produce sensorimotor deficit.³

Radiculopathic pain may be more severe and back pain less severe than that incurred in paramedian disc hernia.³⁻⁵

The exposure of FLDH can often be more complicated than that of routine paramedian herniated lumbar disc.

Several surgical procedures have been used to treat this type of disc herniation. Some are destructive, like hemi / interlaminectomy combined with full of partial facetectomy in order to provide the best exposure but increasing the risk of instability because the wide bone resection.^{1,2,6-8}

Others are more conservative like paramedian muscle splitting approach, preserving stability but offering less exposure of medial foraminal abnormalities.^{5,7,9,10,11,12}

Another possible approach directly exposing the lateral foramen in the transpars approach, with lateral removal or a fenestration of the pars interarticularis.

This approach has been criticized by some authors, who state that this technique offers a limited exposure and has a risk of bone fracture and instability⁷.

Therefore the optimum surgical treatment remains controversial.

This study was undertaken to determine the efficacy and safety of the transpars microscopic approach for the treatment of purely foraminal herniated lumbar disc.

METHODS

This is a two-center prospective study involving patients affected with FLDH treated at Neurosurgery Department of Ferrara University Hospital and at Neurotrauma Department of Catholic University School of Medicine, Rome.

Patients operated from January 2012 to January 2015 were prospectively recruited.

Indications for surgery were persistent radicular pain after minimum 3 weeks of unsuccessful medical therapy and/or presence of nerve root palsy. **Contraindications to**

1 surgery were active cardiovascular disease (acute heart insufficiency, recent myocardial
2 infarction, instable coronary syndrome) and other contraindications to general
3 anesthesia (i.e. pneumonia, sepsis etc...). No patients were excluded from this study.
4

5
6 All patients underwent pre-op MRI and were operated using a microscopic transpars
7 approach. No spondylolisthesis was evident at preoperative MRI. We did not perform
8 preoperative dynamic X-rays due to very intense pain.
9

10
11 Demographic and clinical characteristics were recorded for all patients, including
12 information on drugs intake, working days lost, numeric rating scale (NRS) for pain
13 assessment, nerve root palsy, previous therapy with CT-guided root infiltration(Table1).
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18 19 20 21 *Surgical technique* 22

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24
25 Following general anesthesia, the patient is placed in the prone or in the knee-chest
26 position.
27

28 The operative site is disinfected and the level is identified through a lateral X-ray film.

29 A slightly paramedian incision is made, approximately 1cm from the midline and 3-4
30 cm long.
31

32
33 The subcutaneous tissue is dissected from the underlying fascia. The fascia is then cut
34 close to the lateral aspect of the spinous processes. The multifidus muscle is therefore
35 dissected with a subperiosteal dissection and separated from the spinous process
36 (medially) and the lamina (ventrally). The dissection must then continue laterally, with
37 the help of a Caspar retractor (or a tubular-retractor system), in order to obtain the
38 exposure of the inferior facet joint, the pars interarticularis and the superior facet joint.
39

40 A dissector is placed in the angle formed between the lateral aspect of the pars
41 interarticularis and the superior aspect of the inferior facet joint.
42

43 A lateral X-ray film is performed to confirm the correct level.
44

45 After x-ray confirmation, the operating microscope is used to continue the exposure and
46 dissection. A high-speed-drill removal of the lateral aspect of the pars interarticularis is
47 performed, close to the superior aspect of the inferior facet-joint.
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49 If needed, a very small portion of the superior aspect of the inferior facet joint can be
50 drilled as well. The deepest portion of the pars interarticularis can be removed with
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1 Kerrison rongeurs (Figure 1).
2

3 The ligamentum flavum is therefore opened and removed. The intraforaminal structures
4 are now exposed: the nerve root is usually cranial and the disc space is in the caudal
5 portion of the surgical window (Figure 1).
6

7
8 The herniated lumbar disc is isolated from the nerve root, and removed (Figure 2).
9

10 Once the disc fragment is removed, the disc space is palpated and additional disc
11 material is removed. Complete hemostasis is obtained and the fascia, subcutaneous
12 tissue, and skin are closed in layers in the usual manner .
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19 *Outcome assessment and follow-up*
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23 Patients were followed-up as outpatients at one week after discharge, then at one, six
24 and twelve months.
25

26 A clinical multiparametric evaluation of patients including NRS, drugs intake, Macnab
27 criteria and working days lost was used.
28

29
30 Post-operative dynamic X-rays (flexion, extension) were performed in all cases twelve
31 months after surgery, in order to evaluate possible surgical instability (Figure 3).
32

33
34 Final outcome (twelve month follow-up) was assessed using the Macnab criteria¹³, as
35 follows:
36

- 37
38 - Excellent: No pain; no restriction of activity.
39
40 - Good: Occasional back or leg pain of sufficient severity to interfere with the
41 patient's ability to do his normal work or his capacity to enjoy himself in his leisure
42 hours.
43
44 - Fair: Improved functional capacity, but handicapped by intermittent pain of
45 sufficient severity to curtail or modify work or leisure activities.
46
47 - Poor: No improvement or insufficient improvement to enable increase in activities;
48 further operative intervention required.
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RESULTS

39 patients were enrolled at Ferrara University Hospital and 8 patients were enrolled at Catholic University School of Medicine in Rome, for a total of 47 patients in three years (Jan 2012-Jan 2015). There were 34 males and 13 females, age range was 31-77yo, with an average of 58yo.

These 47 patients represented 5.5% of all patients operated for lumbar herniated disc and 92% of 51 patients with FLDH we observed in that period at the two centers (Table1).

Preoperative clinical and radiological characteristics

No patients were lost at follow-up.

The most involved level was L4-L5 (21 patients 44.7%), L3-L4 (17 patients-36.1%), followed by L2-L3 (7 patients-14.9%) L5-S1 (2 patients-4.3%) .

A preoperative nerve root palsy was present in 40 patients (85.1%).

Preoperative mean NRS score was 8.93 (range 6-10): 32 patients (68.1%) presented a preop NRS of 9 or 10. (see tab 2 for details)

All patients used NSAIDs prior to surgery, 85.1% (40 pts) of patients used steroids, 74.5% (35 pts) of patients were treated with Opioids (see Table 3 for details).

Most patients were given 4 (20 cases, 42.6%) or 5 drugs (7 cases, 14.9%) to treat pain before surgery (see table 4 for details).

Twelve patients (25,55%) underwent CT-guided nerve root injection prior to surgery. None of them presented any clinical improvement.

Twelve patients were retired at the time of the study. For the remaining 35 patients, working days lost prior to surgery were within 15 days in 25.7% of cases, 15 to 30 days in 37.1% of cases, with a median of 30 days and a peak of six months (see table 5 for details).

Outcome analysis

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2
3 No surgery-related complications occurred. Mean hospital stay after surgery was 1,5
4 days (range 1-3 days).

5
6 Among the 35 patients who were not retired at the time of the study, 29 patients
7 returned to work and to normal daily activities within 60 days after surgery. One
8 patients returned to work only after 6 and one patient after 12 months. (see table 5).

9
10 Pain evaluation at discharge showed a significant improvement of NRS score: mean
11 NRS at discharge was 2.45. 21 patients (44.7%) presented a NRS score of 1,
12 2 (7 patients 14.9%) or 3 (7 cases 14.9%) (see table 2 for details). There were only three
13 patients with a NRS of 6 and no patients with a higher score. NRS evaluation at one
14 month follow-up showed a further improvement of the NRS, with a mean value of 1.66
15 At six and at twelve month follow-up we observed no significant variations of NRS
16 (Table 2).

17
18 Root palsy significantly improved in all cases already at one month follow-up. At six
19 and twelve month follow-up, neurological examination was unremarkable for all
20 patients.

21
22 Drugs intake analysis at discharge showed a marked decrease of use of steroids (5
23 cases-10.6%) and Opioids (3 cases-6.4%), and a decrease of NSAIDs (33 cases, 70.2%).
24 At discharge, 7(14.9%) patients had no drugs at all, while 11 patients used drugs only
25 when needed.

26
27 At six-month follow-up, no patients used steroids, or Opioids, 17 patients used NSAIDs
28 when needed, 29 patients (61.7%) used no drugs for pain relief (see table 3 for details).
29 No significant variations occurred at twelve month-follow-up.

30
31 The number of drugs used (including drugs used occasionally for pain relief),
32 significantly decreased too (see table 4).

33
34 At twelve-month follow-up, Excellent or good outcome (Following Macnab criteria)
35 were achieved in 36 (76,6%) and 8 (17%) patients, respectively. There were 3 patients
36 with a fair outcome and no patients with poor outcome.

37
38 There were no cases of frank spinal instability at twelve-month radiological evaluation.
39 Only one asymptomatic patient presented a mild modification in extension of the upper
40 level. Nonetheless, we cannot exclude that mild modification was pre-existing, since
41 pre-operative dynamic x-rays are very difficult to be performed in these patients.

1 No recurrence occurred at follow-up. No re-operations were needed.
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7 *DISCUSSION*
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10 Different surgical approaches have been used for the treatment of purely FLDH.^{1,2,6,7,9,14}
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14 Several authors have advocated the complete removal of the facet joint to allow for
15 decompression of the spinal canal and exploration of the intervertebral foramen. These
16 steps, however, may result in spinal instability and occasionally require posterolateral
17 fusion.¹⁶
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20 Other authors instead prefer to use the paramedian muscle splitting approach (or
21 intertransverse approach). That surgical approach is very elegant and, being lateral to
22 facet joint, is more conservative and preserves stability; nonetheless, the exposure of the
23 medial portion of the foraminal disc is poor.^{5,7,9,10,11,12}
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29 This study was undertaken to evaluate the efficacy of the transpars approach for the
30 treatment of purely FLDH and to assess the safety of this technique.
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33 In our study, we followed-up patients by analysing: NRS, drugs intake, working days
34 lost before and after surgery, nerve root palsy improvement, spinal instability (with
35 dynamic X-rays), thus adding several clinical and radiological outcome measures to
36 MacNab¹³ criteria. In that way, information on outcome was more complete than with
37 MacNab criteria alone.
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42 In the literature, only three authors have radiologically followed patients up during the
43 postoperative period (Garrido⁶, Hejazi⁸, Bernucci²¹). These authors attempted to detect
44 cases of spinal instability after surgery, but they didn't support their evaluation with
45 clinical data.
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49 Four authors (Obenchain¹⁰, Greiner-Perth¹¹, Di Lorenzo²², Bernucci²¹) calculated
50 "working day lost after surgery", but none investigated for "working days lost before
51 surgery"; we believe that this could be a very important outcome parameter.
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55 Obenchain¹⁰ in 2001 was the only author who analysed drugs intake before and after
56 surgery, but he did provide no further clinical or radiological information.
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1 In 2002, Grenier-Perth¹¹ followed-up patients evaluating NRS and nerve root palsy
2 before and after surgery. Nonetheless, he did provide no outcome scale and no
3 radiological evaluation.
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6 Garrido et al. in 1991 analyzed 42 patients after a unilateral complete facetectomy.⁶ In
7 that series, 35 patients (83%) had an excellent outcome, 3 (7,14%) patients had a good
8 outcome, and 3 patients (7,14%) had a poor outcome; one case of spinal instability was
9 detected after radiological evaluation and required lumbar fusion one year later. The
10 same author wrote “three patients had good results with mild residual back and /or leg
11 pain and some restriction of physical activities. In three patients the results were poor
12 with persistent low-back and leg pain and inability to return to work”. We believe that
13 this high percentage of patients with restriction of physical activities and inability to
14 work (14.28%) is quite high for this disease. Therefore, this high complication rate
15 should be considered in order to choose the most appropriate surgical approach.
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19 Epstein’s series of 170 patients is a comparison among several surgical approaches: 73
20 patients (42%) had an excellent outcome, 51 patients (30%) had a good outcome, 26
21 patients (15,3%) had a fair outcome and 20 patients had a poor outcome (11,76%).⁷ In
22 her series, the author had 31 reoperations (25 first operations and 6 second reoperation)
23 and 7 patients (4%) who developed spinal instability after surgery. In her paper the
24 author only calculated the overall number of complications without comparing outcome
25 and complications among different approaches.
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29 Eustacchio in 2002 operated on 80 patients suffering from foraminal and
30 foraminal/extraforaminal herniated lumbar disc by endoscopic percutaneous
31 transforaminal approach: 57,4% patients had an excellent outcome, 34,4% patients had
32 a good outcome, 5,7% patients had a fair outcome and 2,5% patients had a poor
33 outcome; 26 patients (21,3%!) required further reoperation.²³
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37 In 2001, Lew et al published a series of 47 patients operated on with an endoscopic
38 approach. 85 % patients had an Excellent or good outcome, while 4% patients had a fair
39 outcome and 11% patients had a poor outcome and subsequently underwent open
40 surgery.²⁴
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44 In 2012 Liu Tao published a series of 41 patients with a FLDH (in a series of 52
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1 patients), and compared three different approaches: Metrx-a modification of muscle
2 splitting approach-(5 cases), X tube-facetectomy with spinal fusion-(13 cases) and the
3 endoscopy with Yeung Endoscopy Spine System (YESS) technique-23 patients.¹² In
4 YESS group, there were 2 cases of postoperative intervertebral disc inflammation who
5 required other interventions. In Metrx group, 1 case of hematoma was detected and
6 drained. In X-tube group, 1 patient experienced wound hematoma and local infection at
7 the site of iliac incision 1 week after surgery.

8
9
10 Little information exists in the literature on the efficacy and safety of the transpars
11 approach for the treatment of FLDH. The only available series have been published by
12 Di Lorenzo²² et al. in 1998 and Bernucci²¹ et al in 2007. Di Lorenzo published a series
13 of 28 patients, Bernucci²¹ et al published a series of 24 patients. Outcome was excellent
14 or good in all patients, the authors experienced no complications. Both di Lorenzo and
15 Bernucci provided no outcome scales, nor pain evaluation scales, nor drugs intake
16 evaluation, nor information on preoperative working days lost. Most importantly, there
17 is no post-operative radiological evaluation for detecting spinal instability.

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20 Our data show the transpars microscopic approach is a safe and effective technique for
21 the treatment of foraminal herniated lumbar disc.

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24 Moreover, patients in our series and in the series of Di Lorenzo and Bernucci
25 experienced no herniated lumbar disc recurrence and an excellent/good outcome in a
26 very high percentage of patients.

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29 We also believe that adding a radiological follow up to a multi-parameter clinical
30 evaluation is fundamental in order to provide a complete outcome analysis. Other more
31 complete scales evaluating daily and social disability, such as the Oswestry Disability
32 Index, could also be useful.

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35 Larger anatomical and clinical studies comparing efficacy and safety of different
36 approaches for the treatment of FLDH with multiparametric clinical and radiological
37 evaluations are strongly needed.

References

1. Abdullah AF, Ditto EW, 3rd, Byrd EB, et al. Extreme-lateral lumbar disc herniations. Clinical syndrome and special problems of diagnosis. *J Neurosurg* 1974;41:229-34.
2. Abdullah AF, Wolber PG, Warfield JR, et al. Surgical management of extreme lateral lumbar disc herniations: review of 138 cases. *Neurosurgery* 1988;22:648-53.
3. Epstein NE. Foraminal and far lateral lumbar disc herniations: surgical alternatives and outcome measures. *Spinal Cord* 2002;40:491-500.
4. Ohmori K, Kanamori M, Kawaguchi Y, et al. Clinical features of extraforaminal lumbar disc herniation based on the radiographic location of the dorsal root ganglion. *Spine (Phila Pa 1976)* 2001;26:662-6.
5. O'Brien MF, Peterson D, Crockard HA. A posterolateral microsurgical approach to extreme-lateral lumbar disc herniation. *J Neurosurg* 1995;83:636-40.
6. Garrido E, Connaughton PN. Unilateral facetectomy approach for lateral lumbar disc herniation. *J Neurosurg* 1991;74:754-6.
7. Epstein NE. Evaluation of varied surgical approaches used in the management of 170 far-lateral lumbar disc herniations: indications and results. *J Neurosurg* 1995;83:648-56.
8. Hejazi N, Witzmann A, Hergan K, et al. Combined transarticular lateral and medial approach with partial facetectomy for lumbar foraminal stenosis. Technical note. *J Neurosurg* 2002;96:118-21.
9. Maroon JC, Kopitnik TA, Schulhof LA, et al. Diagnosis and microsurgical approach to far-lateral disc herniation in the lumbar spine. *J Neurosurg* 1990;72:378-82.
10. Obenchain TG. Speculum lumbar extraforaminal microdiscectomy. *Spine J* 2001;1:415-20; discussion 20-1.
11. Greiner-Perth R, Bohm H, Allam Y. A new technique for the treatment of lumbar far lateral disc herniation: technical note and preliminary results. *Eur Spine J* 2003;12:320-4.
12. Liu T, Zhou Y, Wang J, et al. Clinical efficacy of three different minimally invasive procedures for far lateral lumbar disc herniation. *Chin Med J (Engl)* 2012;125:1082-8.
13. Macnab I. Negative disc exploration. An analysis of the causes of nerve-root involvement in sixty-eight patients *The Journal of bone and joint surgery. American volume* 1971;53:891-903.
14. Donaldson WF, 3rd, Star MJ, Thorne RP. Surgical treatment for the far lateral herniated lumbar disc. *Spine (Phila Pa 1976)* 1993;18:1263-7.
15. Hazlett JW, Kinnard P. Lumbar apophyseal process excision and spinal instability. *Spine (Phila Pa 1976)* 1982;7:171-6.
16. Hood RS. Far lateral lumbar disc herniations. *Neurosurg Clin N Am* 1993;4:117-24.

17. Jane JA, Haworth CS, Broaddus WC, et al. A neurosurgical approach to far-lateral disc herniation. Technical note. *J Neurosurg* 1990;72:143-4.
18. Lejeune JP, Hladky JP, Cotten A, et al. Foraminal lumbar disc herniation. Experience with 83 patients. *Spine (Phila Pa 1976)* 1994;19:1905-8.
19. Schlesinger SM, Fankhauser H, de Tribolet N. Microsurgical anatomy and operative technique for extreme lateral lumbar disc herniations. *Acta Neurochir (Wien)* 1992;118:117-29.
20. Pirris SM, Dhall S, Mummaneni PV, et al. Minimally invasive approach to extraforaminal disc herniations at the lumbosacral junction using an operating microscope: case series and review of the literature. *Neurosurg Focus* 2008;25:E10.
21. Bernucci C, Giovanelli M. Translaminar microsurgical approach for lumbar herniated nucleus pulposus (HNP) in the "hidden zone": clinical and radiologic results in a series of 24 patients. *Spine (Phila Pa 1976)* 2007;32:281-4.
22. Di Lorenzo N, Porta F, Onnis G, et al. Pars interarticularis fenestration in the treatment of foraminal lumbar disc herniation: a further surgical approach. *Neurosurgery* 1998;42:87-9; discussion 9-90.
23. Eustacchio S, Flaschka G, Trummer M, et al. Endoscopic percutaneous transforaminal treatment for herniated lumbar discs. *Acta Neurochir (Wien)* 2002;144:997-1004; discussion 3-4.
24. Lew SM, Mehalic TF, Fagone KL. Transforaminal percutaneous endoscopic discectomy in the treatment of far-lateral and foraminal lumbar disc herniations. *J Neurosurg* 2001;94:216-20.

*CLINICAL CHARACTERISTICS OF 47 PATIENTS WITH INTRAFORAMINAL DISC
HERNIATION*

AGE	average age 58	range 31-77 years
SEX	34 male patients	13 female patients
SYMPTOMS DURATION	median 2 months, mode 2 months,	range 2 weeks- 2 years
FOLLOW UP	At discharge ,1, 6, 12 months.	
NRS BEFORE SURGERY	range 6-10	mean 8.93 mode 10
NRS AT DISCHARGE	range 1-6	mean 2.43 mode 1
NRS AT 1 MONTH	range 0-4	mean 1.66 mode 1
NRS AT 6 MONTHS	range 0-5	mean 1.55 mode 1
NRS at 12 MONTHS	Range 0-4	mean 1.45 mode 1
LEVELS	L2-L3 7 PATIENTS 14.9% L3-L4 17 PATIENTS 36.1% L4-L5 21 PATIENTS 44.7% L5-S1 2 PATIENTS 4.3%	
SIDE	22 right	25 left
NERVE ROOT PALSY	YES 40 pts (85.1%)	NO 7pts (14.9%)
nerve root infiltration prior to surgery	YES 12pts (25.55%)	NO 35 pts (74.45%)
MEDIAN HOSPITAL STAY	MEAN 1.5 DAYS	RANGE 1-3 DAYS
OUTCOME (12 month follow-up)	<ul style="list-style-type: none"> - Excellent 76,6% (NRS 1 with or without drugs, or NRS 2-3 without drugs) 36 patients - Good 17% (NRS 2-3 with drugs) 8 patients - Fair 6.4% (NRS 4-6) 3 patients - Poor - (NRS > 6 or unchanged) 	

NRS EVALUATION

NRS (0-10)	NRS BEFORE SURGERY	NRS AT DISCHARGE	ONE MONTH FOLLOW UP	SIX MONTH FOLLOW UP	TWELVE MONTH FOLLOW UP
0	-	-	8.5% 4 PTS	14.9% 7 PTS	14.9% 7 PTS
1	-	44.7% 21PTS	51.1% 24 PTS	48.9% 23 PTS	48.9% 23 PTS
2	-	14.9% 7PTS	17% 8PTS	17% 8PTS	19.1% 9 PTS
3	-	14.9% 7PTS	12.8% 6 PTS	10.6% 5 PTS	10.6% 5 PTS
4	-	10.6% 5PTS	10.6% 5PTS	6.4% 3 PTS	6.4% 3 PTS
5	-	8.5% 4PTS	-	2.13% 1 PT	
6	4.25% 2PTS	6.4 % 3PTS	-		
7	4.25% 2 PT	-	-	-	
8	23.4% 11 PTS	-	-	-	
9	29.8% 14 PTS	-	-	-	
10	38.3% 18 PTS	-	-	-	
MEAN	8.93	2.43	1.66	1.55	1.45
MODE	10	1	1	1	1

DRUGS INTAKE BEFORE AND AFTER SURGERY

Drugs	% Before surgery	% At discharge (first week)	% at 6 month follow-up	% at 12 month follow- up
Steroids	85.1% (40pts)	10,6% (5 pts)	0	0
Opioids	74.5% (35pts)	6.4% (3 pts)	0	0
Oxycodone/Naloxone	36,2%(17pts)	0	0	0
Tramadol	8,5%	0	0	0
Other Opioids	36,2%(17 pts)	6.4%	0	0
NSAIDs	100% (47pts)	70.2% (33 pts)	36.2% (17 pts)	36.2% (17 pts)
Ibuprofen	8.5%	0	6.4%*	6.4%*
Ketoprofen	17%	10.6%*	8.5%*	8.5%*
Diclofenac	10.6%(5 pts)	0	6.4%*	6.4%*
Naproxen	8.5%	0	0	0
Nimesulide	8.5%	6.4%*	6.4%*	6.4%*
Ketorolac	8.5%	6.4%*	0	0
Paracetamol	68.1%(32 pts)	19.2%	17%*	17%*
Parac+tramadol	10.6%(5 pts)	0	0	0
Parac+codeine	12.8%(6 pts)	23.4%(11pts)	6.4%*	6.4%*
Other NSAIDs	36.2%(17 pts)	19.2%*	10.6%*	10.6%*
Other drugs				
Pregabalin	17% (8 pts)	17% (8 pts)	2.13% (1 pt)	0
Alprazolam	6.4% (3 pts)	0	0	0
Thiocolchicoside	10.6% (5 pts)	0	0	0
Alpha lipoic acid	6.4% (3 pts)	2.13% (1pt)	2.13% (1 pt)	0
No drugs	0	14.9% (7 pts)	61.7% (29 pts)	61.7% (29 pts)
No Drugs (only when needed)	0	23.41% (11pts)	36.2% (17 pts)	36.2% (17 pts)

NUMBER OF DRUGS USED

N° OF DRUGS	BEFORE SURGERY	AT DISCHARGE	SIX MONTH F-UP	TWELVE MONTH FOLLOW-UP
0	-	12.8% (6 pts)	63.8% (30 pts)	63.8% (30pts)
1	4.25% (2 pts)	48.9% (23 pts)	29.8% (14pts)	34.1% (16pts)
2	17% (8 pts)	38.3% (18 pts)	6.4% (3 pts)	2.13% (1 pts)
3	21.25% (10 pts)	-	-	-
4	42.5% (20 pts)	-	-	-
5	14.9% (7 pts)	-	-	-
MEAN	3.47	1,26	0,43	0,38

Table 5

WORKING DAY LOST BEFORE AND AFTER SURGERY

Working days lost	15D	30D	45D	60D	90D	120D	150D	180D	360D
BEFORE Surgery	25.7% (9 pts)	37.1% (13pts)	-	14.3% (5 pts)	8.6% (3pts)	8.6% (3 pts)	2.85% (1 pt)	2.85% (1 pt)	-
AFTER Surgery	20% (7pts)	34.25% (12pts)	14.3% (5pts)	14.3% (5pts)	8.6% (3pts)	2.85% (1 pt)	-	2.85% (1 pt)	2.85% (1 pt)
MEDIAN BEFORE SURGERY	30DAYS								
MEDIAN AFTER SURGERY	30DAYS								

Figure Legends

Figure 1. Intraoperative view (upper left): the left pars interarticularis is exposed (corresponding saw-bone model in lower left). Intraoperative view (upper right): after removal of the lateral aspect of the pars, the dural sac (black asterisk), the medialized nerve root (black circle) and the herniated disc (white asterisk) are evident. Figure in the lower right shows the intraforaminal exposure on a saw-bone model after removal of the lateral aspect of the pars.

Figure 2. Axial T2 MRI at L3L4 level before (upper left) and after (upper right) surgery. The FLDH and the nerve root are visible within the red circle before surgery. After surgery, a nerve root swelling is visible inside the red circle. The 3D CT scan (lower right) shows the bony window in this case.

Figure 3. flexion-extension Dynamic X-rays at 12 month follow-up. A mild modification of the upper level after surgery visible only in extension (red circle, left image).





