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Comparison of Quality of Life Between Men and Women Who Underwent Transforaminal Percutaneous Endoscopic Discectomy for Lumbar Disc Herniation

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ABSTRACT

Background: Studies describing the efficacy of transforaminal percutaneous endoscopic discectomy (TPED) on shortness of recovery and improvement of postoperative quality of life are limited, especially regarding gender, something that has never been reported before in the literature. The purpose of this study is to evaluate, in accordance with the sex of the patients, possible differences in the health-related quality of life of those who underwent TPED for lumbar disc herniation (LDH).

Methods: A total of 76 patients diagnosed and treated with TPED for LDH with 1-year follow-up were selected and divided into 2 groups of equal number depending on sex. Their quality of life was evaluated by using the 36-Item Short Form Health Survey before the operation, then 6 weeks and 3, 6, and 12 months postoperatively. A statistical analysis was conducted, in order to compare the 8 scaled scores of the 36-Item Short Form Health Survey, each time combining 2 chronological phases for the total number of patients, for each group, and between groups.

Results: Fifty-two (68.4%) patients were \leq 63 years old, whereas the other 24 (31.4%) were >63 years old (mean \pm SD = 56.5 \pm 12.1 years). Apart from the physical function domain, the scores were higher in every visit for the 2 groups, but the change between groups was not significant. Women had a significantly higher increase of physical function score in 3 months after TPED and in the interval 6 weeks to 3 months compared with men. However, in the intervals 3 to 6 months and 3 to 12 months, men presented a significantly higher increase compared with women.

Conclusions: Statistically significant improvement of the quality of life for both men and women was observed. Generally, there was no significant difference between the 2 groups. With regard to the physical functioning, it appears to be a significant difference that is counterpoised over time.

Level of evidence: 2

Clinical relevance: Transforaminal percutaneous endoscopic discectomy for LDH does not present major differences in the improvement of quality of life regarding gender.

Minimally Invasive Surgery

Keywords: lumbar disc herniation, transforaminal percutaneous endoscopic discectomy, minimally invasive spine surgery, gender, quality of life, SF-36

INTRODUCTION

Lumbar disc herniation (LDH) is more common in the lower levels of the lumbar spine and is responsible for the presence of the lumbosacral radicular syndrome, which is a frequently observed problem. The major symptoms of this syndrome are low back pain and sciatica following a dermatomal pattern from below the knee to the feet and toes. Low back pain with sciatica is the main cause of disability and is one of the most prevalent diseases affecting the majority of population on both health and socioeconomics. When

not treated for a long time, it is responsible for relapses of pain and high frequency of work absence.⁵ Low back pain is more frequent in men, but the prevalence is quite high in both sexes.⁶ Other symptoms of the lumbosacral syndrome may include unilateral spasm of the paraspinal muscles, gait deformity, limited forward flexion, muscle weakness, and reflex changes.^{7,8}

In patients with persistent or progressive symptoms after 6 to 12 weeks of conservative treatment (by analgesics or by physical therapy), surgery is indicated. The surgical approach to treatment of LDH includes open discectomy and microdiscec-

tomy. 9,10 Although discectomy is the most frequently performed spinal surgery, it has been replaced by microdiscectomy, which is now the "gold standard" method. 11–13 Improvements in the use of optics and surgical instruments have led to the use of full-endoscopic minimally invasive surgical procedures. As a result, endoscopy has become popular among spinal surgeons over the last decades and can be performed with a posterior or posterolateral approach. 14 The search for newer surgical techniques to achieve the aims of minimally invasive surgery, including limited skin incisions and decreased muscle damage, has made transforaminal percutaneous endoscopic discectomy (TEPD) a promising minimally invasive surgical procedure recently.

Transforaminal percutaneous endoscopic discectomy approaches the epidural space through the Kambin's triangle and combines the benefits of endoscopy (direct visualization, reduced trauma, reduced blood loss, shorter hospital stays, less pain, quicker recovery, and postoperative morbidity) with optimal exposure of the intervertebral space and preservation of the dorsal musculature, the vertebrae, and the ligamentous structures. 15-17 No paraspinal muscle is cut or detached from the insertion. The minimal tissue damage during TEPD could make a difference in effectiveness, faster rehabilitation, and thus lower costs for society. There are several studies comparing the safety and efficacy of TEPD with those of microdiscectomy; however, there is no comparison between men and women who underwent this minimally invasive surgery. Men, in contrast to women, have generally greater muscle mass but slightly higher body mass index (BMI), which, hypothetically, could alter the postsurgical recovery. Thus, we considered that some differences based on gender characteristics might exist between our 2 groups. This study examines our experience using this technique to improve early recovery after surgery treating LDH in accordance with sex.

PATIENTS AND METHODS

Patients

All patients of our study were diagnosed with LDH, and they had fulfilled all the indications for discectomy. They were all referred to the same orthopedic spine surgeon, and all the procedures were performed at the same hospital. Patients agreed to participate in the study and signed a fully

informed written consent. The study was approved by the medical council of the hospital and the local ethics committee.

Inclusion criteria were (2) radiculopathy, (2) positive nerve root tension sign, (3) sensory or motor neurologic lesion on clinical examination, (4) hernia confirmed by MRI of the lumbar spine, in compliance with clinical findings, and (5) failure of a 12-week conservative treatment.

Exclusion criteria were (1) noncontaminated disc hernia exceeding one third of the spinal canal on the sagittal MRI scans, (2) sequestration of the disc, (3) central or lateral recess spinal stenosis, (4) recurrent herniated disc or previous surgery at the affected level, (5) segmental instability or spondylolisthesis, (6) spinal tumor or infection, and/or (7) vertebral fracture.

Methods

This is a prospective cohort study involving patients who underwent TPED for LDH. In general, 103 patients underwent spine surgery throughout the season 2014–2015. Of those, 76 patients were selected to participate in a 1-year follow-up; they were divided into 2 groups according to sex. Their health-related quality of life was evaluated by using the 36-Item Short Form Health Survey (SF-36). Patients were asked to complete the measurements right before surgery. The 8 dimensions of the SF-36, including PF, RP, BP, GH, VT, SF, RE and MH, were measured and reassessed at 6 weeks, 3 months, 6 months and a year after the TPED. Our primary hypothesis was that some of the 8 scaled scores of the SF-36 would differ significantly between men and women a year after TPED.

Surgical Technique

The TEPD was performed under local anesthesia and mild sedation. All patients were monitored in terms of blood pressure, pulse rate, oxygen saturation, and electrocardiographic signals. Patients were positioned at the lateral decubitus position, lying down on the opposite site in order for the lesion to face upward. After disinfection of the surgical field, local anesthesia was initially performed at the needle entry site. The needle was placed through the Kambin's triangle 11 cm from the midline, under fluoroscopic technique (Figure 1). After verification of the level, mild sedation and analgesia were provided with fentanyl (ampule) because the en-

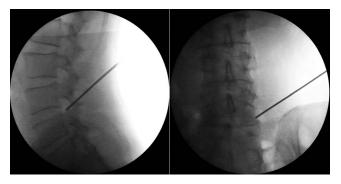


Figure 1. Anteroposterior (right) and lateral (left) intraoperative fluoroscopic images of the guide wire placed at the level where the disc herniation is present.

largement of the neural foramen is painful. The compliance of the patients was affected during the sequential passage of 3 different size reamers (5.5, 6.5, 7.5 mm, Joymax System). The cannula and the endoscope were then placed and the nerve root was secured. Subsequently, the discectomy was performed with graspers (Figure 2). The patients were monitored for the following hour in the wards and then mobilized.

SF-36 Scoring Scale

The scale has 36 items. Item 2 is self-reported health changes and does not contribute to the score. The remaining 35 entries constitute 8 dimensions: physiological function (physical functioning [PF]), physical function (role physical), bodily pain (bodily pain), general health (general health), energy (vitality), social function (social functioning), emotional function (role emotional), and mental health (mental health). The higher the total score of these 8 dimensions, the better the quality of life survey. If respondents answer fewer than half the number of entries, then their questionnaires were considered invalid. ¹⁹

Statistical Analysis

The statistical analysis of this study was performed with the statistical package SPSS, version 17.00 (SPSS Inc, Chicago, Illinois). A *P* value < .05 was determined as a statistically significant difference level. Continuous variables (age, SF-36 score)



Figure 2. Intraoperative endoscopic visualization of the annular opening of the working channel. With the rongeur it is possible to remove the herniated disc material.

are expressed as mean ±z standard deviation (SD) and categorical variables (gender) are expressed as percentages. We used the Student t test and Mann-Whitney U test for quantitative-continuous variables, for normal or nonnormal distribution, respectively, and Wilcoxon signed-rank test for repeated measurements on a single sample (total of patients, group A [men] and group B [women]) to assess whether the mean ranks differ in each of the 8 scaled scores. The SF-36 measures were assessed before the operation, 6 weeks, 3 months, 6 months, and a year after the TPED. We studied whether there was any significant difference in the 8 scaled scores of SF-36 between 2 chronological phases in the total of patients, in each group, and between groups.

RESULTS

Group A consisted of 38 (50%) male patients, including those who had been diagnosed with LDH, and group B consisted of 38 (50%) female patients, including those who had been diagnosed with LDH. Regarding the LDH level, 21 (27.6%) was presented at L3-L4, 40 (52.6%) at L4-L5 and 15 (19.7%) at L5-S1 (Table 1). Of 76 patients, 52 (68.4%) patients

Table 1. Demographic and baseline characteristics.

	Count, n (%)	Age, Mean \pm SD	L3-L4, n (%)	L4- L5, n (%)	L5-S1, n (%)
Total	76 (100)	56.47 ± 12.066	21 (27.6)	40 (52.6)	15 (19.7)
Male	38 (50)	56.53 ± 12.63	11 (28.9)	20 (52.6)	7 (18.4)
Female	38 (50)	56.42 ± 11.64 t test, $P = .970$	10 (26.3)	$\begin{array}{c} 20 \ (52.6) \\ \chi^2, \ P = .944 \end{array}$	8 (21.1)

 Table 2.
 Preoperative estimation of mean values of SF-36 for men and women.

	PF Pre-op,	RP Pre-op,	BP Pre-op,	GH Pre-op,	V Pre-op,	SF Pre-op,	RE Pre-op,	MH Pre-op,
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Total Male Female	47.38 ± 7.207 47.68 ± 8.441 47.08 ± 5.819 t test, P = .717	21.96 ± 5.672 22 ± 6.164 21.92 ± 5.216 Mann-Whitney $U, P = .963$	31.43 ± 5.36 31.34 ± 5.45 31.53 ± 5.34 t test, P = .882	64.5 ± 4.743 64.37 ± 4.978 64.63 ± 4.558 Mann-Whitney $U, P = .988$	46.3 ± 5.143 46.39 ± 4.659 46.21 ± 5.648 t test, $P = .877$	50.71 ± 6.659 50.76 ± 6.284 50.66 ± 7.099 t test, P = .946	50.87 ± 7.08 50.89 ± 6.88 50.84 ± 7.37 t test, $P = .974$	70.83 ± 7.641 70.79 ± 7.868 70.87 ± 7.513 t test, P = .989

Abbreviations: SF-36, 36-Item Short Form Health Surgery; PF, physical function; RP, role physical; BP, bodily pain; GH, general health; V, vitality; SF, social function; RE, role emotional; MH, mental healti

were \leq 63 years old, whereas the other 24 (31.4%) were >63 years old (mean \pm SD = 56.5 \pm 12.1 years). The two subpopulations (men and women) do not have statistically significant differences, something which is important because the groups under comparison have similar starting characteristics (Table 2).

The mean BMI was 29.3 ± 1.2 for men and 28.8 ± 1.1 for women. The mean operative time was 32.1 ± 2.3 minutes and the blood loss limited. All patients underwent the procedure successfully without conversion to open surgery. The patients were discharged 1 day after surgery. There were no intraoperative complications. There were few post-operative complications and they were temporary. One patient presented hypoesthesia on the lower extremity, and 2 presented neurogenic dysfunction, which was absent after 1 month. In addition, 2 furcal nerves were found in 2 patients. None of the patients underwent a revision surgery.

All selected patients successfully reached the end of the follow-up. Thus, the percentage of the 1-year follow-up is 100%. The increase of all 8 scaled scores of SF-36 between 2 chronological phases and in all intervals was statistically significant ($P \leq .05$) in the total of patients and in each group separately (Table 3). Physical role functioning, bodily pain, general health, vitality, social role functioning, emotional role functioning, and mental health scores were higher in every visit for the 2 groups, but the change between groups was not significant (P > .05).

Group B (women) had a significantly higher increase in the PF score in the 3 months after TPED (P=.023) and in the interval 6 weeks to 3 months (P<.001) compared with group A (men). However, in the intervals 3 to 6 months and 3 to 12 months, group A presented a significantly higher increase in the PF score (P=.025 and P=.007, respectively) compared with group B. At the end of a year follow-up, physical function was increased by 35.2 (± 5.9) in group A and 35.9 (± 5.1) in group B (P<.001).

Regarding the graphic representations, the SF-36 scores preoperatively and at 6 months and 1 year postoperatively showed statistically significant increases in all 8 domains for men and women separately and in the total number of patients (Figures 3 and 4). Changes in SF-36 scores at 6 months and 1 year compared with before surgery showed no statistically significant differences for all 8 domains between men and women (Figure 5).

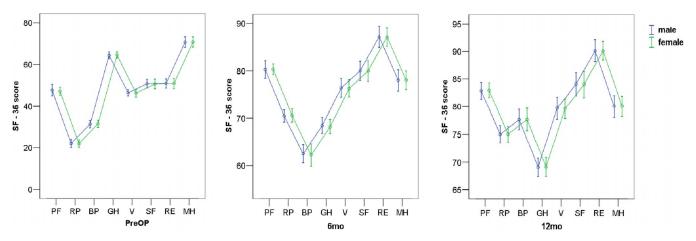


Figure 3. The 36-Item Short Form Health Survey (SF-36) scores preoperatively, at 6 months, and at 1 year postoperatively, related to gender. Abbreviations: PF, physical function; RP, role physical; BP, bodily pain; GH, general health; V, vitality; SF, social function; RE, role emotional; MH, mental health.

DISCUSSION

There has been an increasing interest in the effect of sex in scientific and clinical research. We considered this to be an interesting comparison, because men, in contrast to women, have generally greater muscle mass but slightly higher BMI. Hypothetically, this could play a significant role in the postsurgical recovery of men and women. The results of this study showed statistically significant improvement in health-related quality of life, including physical role functioning, bodily pain, general health, vitality, social role functioning, emotional role functioning, and mental health, in every postoperative visit for both male and female

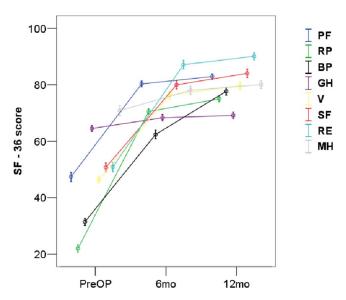


Figure 4. The 36-Item Short Form Health Survey (SF-36) scores in total sample, preoperatively, at 6 months and at 1 year postoperatively. Abbreviations: PF, physical function; RP, role physical; BP, bodily pain; GH, general health; V, vitality; SF, social function; RE, role emotional; MH, mental health.

patients. In general, the change between the 2 groups was not significant. Thus, TPED does not present differences between men and women.

With regard to the PF domain, women had a significant higher increase in the PF score in the 3 months after TPED and in the interval 6 weeks to 3 months, compared with men; however, men presented significantly a higher increase in the PF score in the last three quarters of the 1-year follow-up, in contrast to women. Thus, this difference is counterpoised over time and does not have major clinical importance. The PF domain includes many activities, some vigorous (such as running, lifting heavy objects), others moderate (such as moving a table, carrying groceries, climbing stairs, bending, walking). Men included in this study probably had more demanding physical functioning in their normal routine than the women and also a slightly higher BMI, which leads to more difficulty and a limitation of typical activities. Nevertheless, men presented a significantly higher increase of PF score in the intervals 3 to 6 months and 3 to 12 months when compared with women. An explanation for this could be the fact that at this point, the recovery of the nerve root is completed and the greater muscle mass of men contributes to improvement in former daily activities.

There are several studies that indicate the role of TEPD as a minimally invasive surgery with multiple advantages, especially in single-level herniations. However, studies of TEPD for LDH describing its safety and efficacy are limited. There are two systematic reviews which conclude that TPED appears to be a safe and effective intervention for LDH and has similar clinical outcomes compared with conventional open micro-

Table 3. Comparison of change of mean values for all chronological phases (2 phases each time) for men and women (mean ± SD).

Domain	Pre-op to 6 wk	Pre-op to 3 mo	Pre-op to 6 mo	Pre-op to 12 mo	6 wk to 3 mo	6 wk to 6 mo	6 wk to 12 mo
PF							
Male Female	16.9 ± 5.6 17.1 ± 4.4 t test P = .87	22.9 ± 5.8 25.8 ± 5.2 t test P = .023	32.6 ± 6.9 33.3 ± 5.3 Mann-Whitney P = .52	35.2 ± 5.9 35.9 ± 5.1 t test P = .58	6.0 ± 3.1 8.7 ± 3.0 Mann-Whitney P < .001	15.7 ± 4.5 16.2 ± 3.0 Mann-Whitney P = .40	18.3 ± 3.5 18.8 ± 3.2 Mann-Whitney P = .51
RP							
Male Female	35.29 ± 5.0 35.63 ± 3.3 t test 0.726	43.61 ± 5.84 44.0 ± 3.79 Mann-Whitney 0.508	48.45 ± 5.75 48.66 ± 3.66 Mann-Whitney 0.967	53.0 ± 6.33 53.11 ± 3.95 Mann-Whitney 0.975	8.32 ± 3.30 8.37 ± 2.48 Mann-Whitney 0.998	3.16 ± 3.69 13.03 ± 2.60 t test 0.858	17.71 ± 5.04 17.47 ± 3.47 $t \text{ test}$ 0.237
BP							
Male Female	16.03 ± 4.42 16.0 ± 3.43 Mann-Whitney 0.715	21.55 ± 4.91 21.16 ± 4.23 t test 0.708	31.18 ± 5.52 30.71 ± 5.65 t test 0.713	46.32 ± 5.71 46.16 ± 5.69 t test 0.904	5.53 ± 2.03 5.16 ± 1.63 Mann-Whitney 0.467	15.16 ± 3.65 14.71 ± 3.54 Mann-Whitney 0.696	30.29 ± 4.75 30.16 ± 4.51 t test 0.902
GH Male	0.95 ± 1.66	2.42 ± 1.57	4.08 ± 2.37	4.74 ± 2.48	1.47 ± 2.53	3.13 ± 2.98	3.79 ± 3.12
Female	1.00 ± 1.72 Mann-Whitney 0.857	1.89 ± 2.09 Mann-Whitney 0.234	3.55 ± 3.06 Mann-Whitney 0.725	4.74 ± 2.46 4.53 ± 2.65 Mann-Whitney 0.962	0.89 ± 2.71 Mann-Whitney 0.411	2.55 ± 3.32 Mann-Whitney 0.601	3.79 ± 3.12 3.53 ± 3.00 Mann-Whitney 0.802
V	0.037	0.23 1	0.723	0.902	0.111	0.001	0.002
Male Female	11.92 ± 3.42 12.05 ± 2.56 Mann-Whitney 0.549	17.0 ± 4.55 17.0 ± 3.65 Mann-Whitney 0.782	30.0 ± 5.88 30.05 ± 5.20 <i>t</i> test 0.967	33.34 ± 6.02 33.42 ± 5.60 t test 0.953	5.08 ± 2.39 4.95 ± 2.82 Mann-Whitney 0.745	18.08 ± 4.89 18.0 ± 4.73 t test 0.943	21.42 ± 5.0 21.37 ± 5.22 <i>t</i> test 0.964
SF							
Male Female	13.26 ± 4.13 13.26 ± 3.68 Mann-Whitney 0.917	15.32 ± 4.28 15.34 ± 3.92 t test 0.978	29.24 ± 6.22 29.32 ± 5.08 <i>t</i> test 0.958	33.32 ± 6.46 33.34 ± 6.37 t test 0.986	2.05 ± 1.97 2.08 ± 1.68 t test 0.95	15.97 ± 5.89 16.05 ± 4.14 Mann-Whitney 0.988	20.05 ± 5.86 20.08 ± 5.26 t test 0.984
RE							
Male Female	17.16 ± 4.99 17.18 ± 5.52 Mann-Whitney 0.843	25.68 ± 6.41 25.66 ± 5.23 t test 0.984	36.24 ± 7.06 36.26 ± 5.44 t test 0.986	39.21 ± 6.59 39.26 ± 5.19 <i>t</i> test 0.969	8.53 ± 3.74 8.47 ± 3.93 t test 0.953	19.08 ± 5.59 19.08 ± 4.18 Mann-Whitney 0.917	22.05 ± 5.64 22.08 ± 4.27 t test 0.982
MH							
Male Female	1.74 ± 1.62 1.79 ± 2.00 t test 0.901	4.53 ± 2.14 4.42 ± 2.52 t test 0.845	7.21 ± 2.91 7.16 ± 3.15 t test 0.941	9.26 ± 3.38 9.21 ± 3.86 <i>t</i> test 0.951	2.79 ± 1.37 2.63 ± 1.42 Mann-Whitney 0.673	5.47 ± 2.33 5.37 ± 2.55 Mann-Whitney 0.875	7.53 ± 2.78 7.42 ± 3.14 Mann-Whitney 0.875

Abbreviations: PF, physical function; RP, role physical; BP, bodily pain; GH, general health; V, vitality; SF, social function; RE, role emotional; MH, mental health.

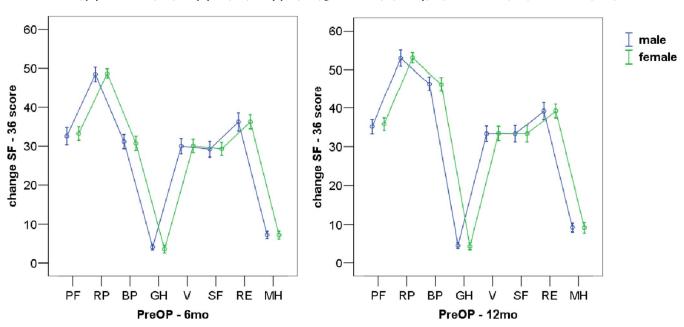


Figure 5. Change in 36-Item Short Form Health Survey (SF-36) scores at 6 months and at 1 year compared with before surgery, related to gender. Abbreviations: PF, physical function; RP, role physical; BP, bodily pain; GH, general health; V, vitality; SF, social function; RE, role emotional; MH, mental health.

Table 3. Extended.

3 to 6 mo	3 to 12 mo	6 to 12 mo
9.7 ± 4.3	12.3 ± 3.5	2.6 ± 3.1
7.5 ± 3.0	10.1 ± 3.5	2.6 ± 1.8
Mann-Whitney	t test	Mann-Whitney
P = .025	P = .007	P = .91
4.84 ± 1.89	9.39 ± 4.78	4.55 ± 4.43
4.66 ± 1.53	9.25 ± 3.81	4.45 ± 2.06
Mann-Whitney	Mann-Whitney	Mann-Whitney
0.646	0.271	0.356
9.63 ± 2.84	24.76 ± 4.80	15.13 ± 53.78
9.55 ± 2.95	25.0 ± 4.34	15.45 ± 4.26
Mann-Whitney	<i>t</i> test	Mann-Whitney
0.901	0.822	0.65
1.66 ± 1.83	2.32 ± 1.87	0.66 ± 1.80
1.66 ± 1.91	2.32 ± 1.87	0.97 ± 1.93
Mann-Whitney	Mann-Whitney	Mann-Whitney
0.891	0.496	0.425
13.0 ± 4.04	16.34 ± 4.28	3.34 ± 1.53
13.05 ± 3.91	16.42 ± 4.37	3.37 ± 1.87
Mann-Whitney	Mann-Whitney	Mann-Whitney
0.738	0.937	0.811
13.92 ± 5.43	18.0 ± 5.41	4.08 ± 1.38
13.97 ± 3.56	18.0 ± 4.83	4.03 ± 2.32
Mann-Whitney	Mann-Whitney	Mann-Whitney
0.933	0.954	0.603
10.55 ± 3.95	13.53 ± 4.09	2.97 ± 1.78
10.61 ± 2.61	13.61 ± 3.34	3.00 ± 2.02
Mann-Whitney	Mann-Whitney	Mann-Whitney
0.773	0.983	0.895
2.68 ± 1.31	4.74 ± 2.22	2.05 ± 1.52
2.74 ± 2.39	4.79 ± 3.16	2.05 ± 1.69
Mann-Whitney	Mann-Whitney	Mann-Whitney
0.502	0.962	0.958

discectomy.^{21,22} Even more promising results come from a recent systematic review and meta-analysis that compared endoscopic discectomy versus open microdiscectomy and found a significantly higher satisfaction rate in patients who underwent endoscopic discectomy.²³ Statistically significant and clinically relevant sex differences were found in other studies also. In a relative study for LDH treated with microdiscectomy, at 1-year follow-up, women reported a higher degree of postoperative back and leg pain along with less improvement regarding disability and some aspects of quality of life; however, the surgical effect was similar.²⁴

The present study has several limitations. Due to the design, there was no proper control group because the objective of this study was not to emphasize the possible advantages of TEPD over other procedures but to present its early results on the improvement of the quality of life of patients. We did not want to include the widely used Oswestry Low Back Pain Questionnaire and Visual Analog Scale because we consider SF-36 to be a multi-scaled questionnaire that is more complete, including emotional and mental sections. Furthermore, it would increase the significance of our study results if we considered designing 1 more year of follow-up to achieve a 2-year period. This did not happen because we wanted to present our early clinical findings on these patients.

Even though several studies regarding TPED for the treatment of LDH exist, none of them has investigated the differences of the improvement of the health-related quality of life between men and women. Transforaminal percutaneous endoscopic discectomy is associated with many advantages in that it preserves the biomechanics of the lumbar spine, offers stability to the operated and adjacent level, and reduces traumatization of the supportive paraspinal tissues. On the basis of our findings, TEPD seems to be a secure and efficient technique with significant improvement of the quality of life of men and women during the 1-year follow-up for the treatment of LDH. Indeed, few differences were observed between the 2 groups; however, those had minor clinical impact. Nevertheless, this topic should be further researched with high-quality randomized controlled trials that also assess costeffectiveness.

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