Randomized Controlled Trial

Radiofrequency Denervation on Lumbar Facet Joint Pain in the Elderly: A Randomized Controlled Prospective Trial

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Disclaimer: Yu Si Chen and Botao Liu are co-first authors.
Fund source: National key R & D project of China (No. 2020YFC2007304).

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 02-12-2022
Revised manuscript received: 06-29-2022
Accepted for publication: 08-16-2022

Free full manuscript: www.painphysicianjournal.com

Background: Lumbar facet joint (LFJ) pain is the most common cause of low back pain in the elderly. Denervation of the medial branch of the spinal dorsal ramus can theoretically achieve long-term pain relief. Yet there is little evidence of high-level prospective randomized controlled research.

Objectives: To observe the effect of radiofrequency (RF) denervation of the medial branch of the spinal dorsal ramus on LFJ pain in the elderly.

Study Design: A prospective randomized controlled study.

Setting: The study was performed in the National Pain Management and Research Center of China-Japan Friendship Hospital.

Methods: A total of 270 patients over 60 years old with LFJ pain were randomly divided into an RF group (n = 135) and a control group (n = 135). They received radiofrequency denervation intervention and a conventional conservative approach, respectively. The follow-up was 6 months. The main outcome was the NRS pain score (0-10 points) and the proportion of patients with a pain reduction of more than 2 points (minimum difference of clinically significant difference). The secondary outcome was the Oswestry Disability Index (ODI), the proportion of patients whose ODI decreased by more than 15 points, and the Macnab standard efficacy evaluation. The factors that influenced the excellent and good Macnab rates were analyzed by univariate and multivariable regression analysis.

Results: There were more women than men who suffered from LFJ (171/99) pain based in these 270 patients. The numeric rating scale (NRS) pain score changes in the RF group were significantly different from those in the control group at the 1st, 3rd, and 6th months (-2.3 vs -1.2, -2.0 vs -1.2, -2.0 vs -1.1, $P < 0.001$), and the proportion of patients whose NRS decreased by ≥ 2 was higher than that in the control group at the 3rd and 6th months (61.1% vs 26.0%, 52.9% vs 22.5%, $P < 0.001$). The ODI score changes in the RF group were significantly different from that in the control group at the 1st, 3rd, and 6th months (-15.2 vs -10.1, -14.6 vs -8.6, -13.6 vs -7.7, $P < 0.001$), and the proportion of ODI reduction ≥ 15 was also higher than that in the control group at the 3rd and 6th months (45.8% vs 34.1%, 36.4% vs 27.0%, $P < 0.05$). The excellent rate and efficiency of the Macnab evaluation in the RF group at the 6th month was significantly higher compared to the control group (60.3% vs 36.0%, 81.0% vs 54.1%, $P < 0.001$). The independent factor affecting the excellent and good rate is failed back surgery syndrome.

Limitation: The limitation of this study is that it was only performed in one unit of the National Pain Management and Research Center. It needs to be further carried on in multiple centers in the future.

Conclusions: Radiofrequency denervation can effectively reduce LFJ pain and improve movement disorder. The effect is good until 6 months later.

Key words: Elderly, radiofrequency denervation, lumbar facet joint, medial branch

Pain Physician 2022: 25:569-576

Lumbar facet joint (LFJ) pain is defined as pain originating from any structure integral to both the function and configuration of the lumbar facet joints, including the fibrous capsule, synovial membrane, hyaline cartilage surfaces, and bony articulations. About 15% to 52% of patients with chronic low back pain are attributed to facet lesions (1-2). The prevalence rate in the elderly is significantly increased (3), as 20% to 25% of elderly people over 65 years old suffer from LFJ-derived pain (4).

Radiofrequency ablation (RFA) of the medial branch nerves (MBN) is commonly used in LFJ pain treatment. The medial branch of the spinal dorsal ramus is the only sensory nerve innervating LFJ and, therefore, the only afferent pathway for its pain signal. The anatomical position of the medial branch is relatively fixed. Denervation of the medial branch can theoretically achieve long-term pain relief. However, studies have demonstrated differing results on LFJ pain management by RFA (5-8), and there is little evidence of prospective randomized controlled research of long-term efficiency.

Methods

Inclusion and Exclusion Criteria

The study was performed in the National Pain Management and Research Center of the China-Japan Friendship Hospital. Inclusion criteria: 1) Patients over 60 years old who have experienced chronic low back pain for at least 3 months; 2) Unilateral or bilateral low back pain, with numeric rating scale (NRS) score ≥ 4. The lumbar pain is aggravated by movement and relieved at rest. The pain can radiate to the hip and groin (the radiating pain does not exceed the knee). Physical examination shows lumbar paravertebral pressure pain; 3) MRI or CT of the lumbar spine shows one of the following manifestations: articular process hyperplasia or marginal osteophyte formation, joint capsule or surrounding tissue calcification; 4) Patients must have received nonsteroidal anti-inflammatory agents (NSAIDs) for one week without pain relief or be unwilling to continue taking NSAIDs. Exclusion criteria: 1) Severe heart, lung, brain, liver, kidney, and blood diseases; 2) Tumor infection, fracture, tuberculosis, and other specific low back pain; 3) Inability or unwillingness to cooperate. 4) Negative results from 1% lidocaine 0.5 mL diagnostic block (pain relief no more than 50%). The study was approved by the ethics committee of China-Japan Friendship Hospital (2018-135-Q17), and the registration number of the China Trial Clinical Registration Center was CHICTR210043293. All patients signed informed consent.

Surgical Instruments and Equipment

- RF Generator: American Cosman G4
- Radiofrequency ablation needle: 20G×150×5, Emmendingen Medical Technology Co., Ltd. in Norman, Germany

Grouping and Intervention

Patients were randomized using a computerized random number generator, accessed through a password-protected website, and maintained independently. Patients were allocated (1:1) to the RF group or the control group. The control group was treated with nonsteroidal analgesic drugs, glucosamine sulfate, physical therapy, and exercise rehabilitation. Patients and caregivers were not blinded. Data handling, analysis, and interpretation of results were conducted blindly.

The patient lay prone on the operating table with a pillow under the abdomen in order to flatten the lumbar lordosis. Under sterile technique, local anesthesia, and fluoroscopic guidance, the medial branch nerves innervating the symptomatic facet joint, as identified by the diagnostic blocks, were lesioned. The RF cannula was placed at the junction of the superior articular and transverse processes (Figs. 1-2). For the L5 medial branch, the electrode was placed at the junction of the S1 superior articular process and the sacral ala (Fig. 3). The electrical stimulation test was started; 50 Hz, 0.3-0.6 V stimulation induced pain in the corresponding innervated area without exceeding the knee joint. Motor stimulation of 2Hz was applied to ensure multifidus muscle without leg muscle twitching occurred. The RF denervation parameters were: width 20ms, frequency 2Hz, voltage 40-60V, temperature 75°C with a duration of 120s. The second lesion was performed with the electrode positioned at the junction of the superior and inferior facet joints. All lesion sites were anesthetized using 1% lidocaine 1mL.

Observation Indicators

All patients were followed by telephone or outpatient visits before treatment and at the 1st, 3rd, and 6th months after treatment.

The main outcomes were the NRS pain score (0-10 points), 0 painless, 10 most severe pain, and the proportion of patients with pain reduction of more

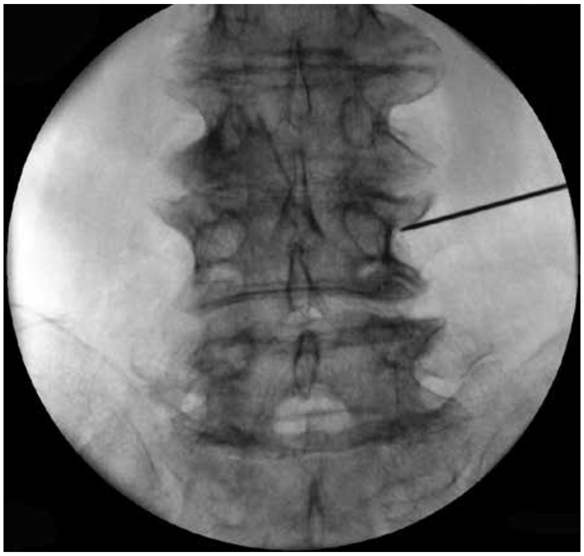

Fig. 1. *Radiofrequency of the L3 medial branch of spinal dorsal ramus.*

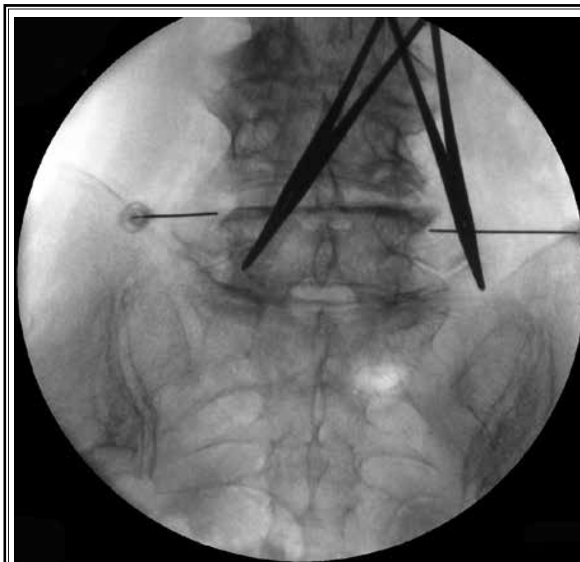

Fig. 2. *Radiofrequency of the L4 medial branch of spinal dorsal ramus (bilateral).*

than 2 points (minimum difference of clinical significance) (9).

The secondary outcome was Oswestry Disability Index (ODI) (10) and the proportion of patients whose ODI decreased by more than 15 points (minimum difference of clinical significance) (11). The ODI is a quantitative evaluation table of dysfunction in patients with low back pain, including 10 questions: pain, self-care, lifting, walking, sitting upright, standing, sleep, sexual life, social activities, and tourism. Each answer is given a score of 0-5 points. Accumulating the 10 answers gives the ODI index. The higher the score, the more serious the dysfunction.

The secondary outcome measures also included the Macnab standard efficacy evaluation (12), excellent: pain disappeared after treatment, no activity dysfunction, and returned to normal work and life; Good: the pain basically disappeared, with mild symptoms and mild activity restriction, which hardly affected the normal work and life; Average: the symptoms are improved to a certain extent, but there is still pain, which has an impact on daily work and life; Poor: no improvement in clinical symptoms and signs. Total effective rate = (excellent + good + average) / total cases * 100%, excellent rate = (excellent + good) / total cases * 100%. The influencing factors of excellent and good curative effect rates were analyzed by univariate and multivariable regression analysis.

Fig. 3. *Radiofrequency of the L5 medial branch of spinal dorsal ramus.*

Sample Size and Statistics

A clinically relevant mean difference of 2 points or more on the NRS for pain intensity was used for the sample size calculation (12). With a power of 0.9, a 2-sided α of .05, and a correlation of 0.5 for repeated measurements, 85 patients per group were needed. Anticipating potential study withdrawal (20%), a minimum of 200 patients was needed.

SPSS version 18.0 statistical software (IBM Corporation, Chicago, IL) was used for analysis. The measurement data of normal distribution was compared by t-test, expressed by mean ± standard deviation test. The measurement data of skewed distribution were compared by a rank sum test, expressed by median interquartile spacing [M (q)]. The comparison of counting data was compared by chi-squared test, and the rank sum test was used for grade data. Multivariable regression analysis was used to analyze the related factors between the main indexes and to explore the related factors affecting the curative effect. The intention to treat (ITT) principle was adopted for all statistical analyses. Patients who received treatment and completed the first follow-up can be included in the statistics. The lost data was carried forward by the last observation carried forward method ($P < 0.05$).

Results

General Information

From May 2018 to May 2021, 432 patients met the inclusion criteria at the National Pain Management and Research Center of China-Japan Friendship Hospital. One hundred and sixty-two patients were excluded: 10 cases of serious cardiovascular and cerebrovascular diseases, 12 cases were unable or unwilling to participate, 2 cases had infection or tumor at the puncture site, and 138 cases had less than 50% pain relief in the lidocaine test. Finally, 270 cases met the inclusion criteria and were randomly divided into the RF group (n = 135) and the control group (n = 135). During the follow-up, 9 cases in the RF group underwent other lumbar surgery, and 5 cases were lost to follow-up. In the control group, 20 cases underwent other lumbar surgery, and 4 cases were lost to follow-up (Fig. 4).

Among the 270 patients with low back pain included in the study, there were 110 patients with bilateral LFJ pain, 41 cases of intervertebral disc degeneration (disc height reduction, disc vacuum sign, Schmorl nodule, endplate inflammation), 58 cases of failed back surgery syndrome (FBSS), 23 cases of ligament calcification and 85 cases of lower limb radiating pain. There were more women than men (171 vs 99), and there was no significant difference in other clinical characteristics between the 2 groups (Table 1). Lumbar facet joint pain is the most common in L4/L5 and L5/S1 facet joints (81.5% and 77.8%) in this study. These patients got L3, L4, and L5 medial branch and facet joint RFA.

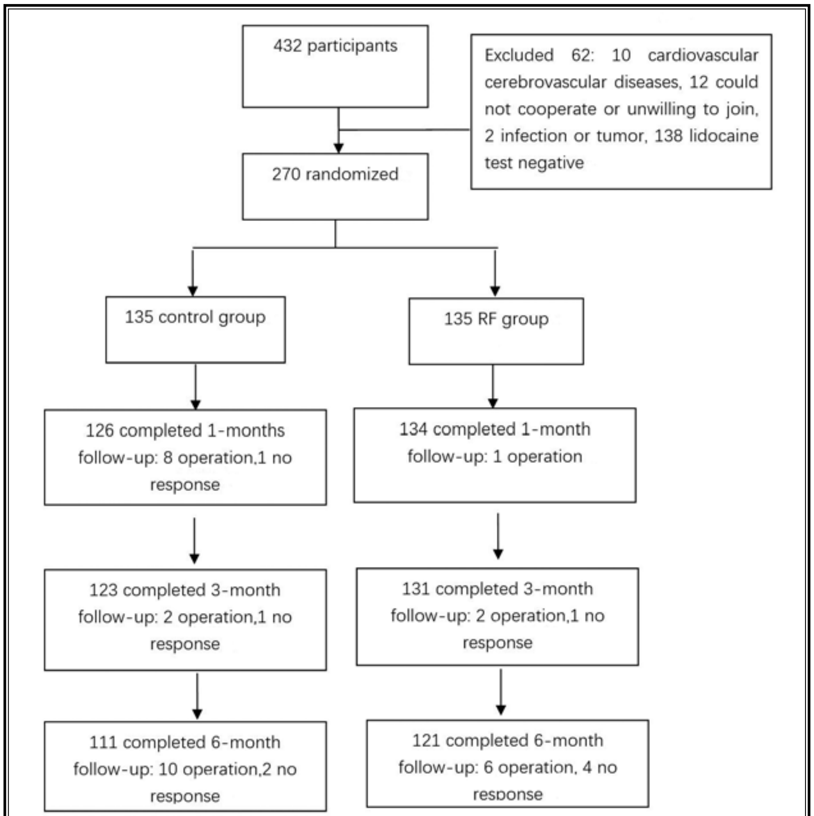

Fig. 4. *Flow of patients through the trial.*

The change of NRS score in the RF group was significantly higher than that in the control group at the 1st, 3rd, and 6th month (-2.3 vs-1.2, -2.0 vs -1.2, -2.0 vs -1.1, $P < 0.001$). The proportion of patients with a decrease of NRS ≥ 2 was also significantly higher than that in the control group at the 3rd and 6th month (61.1% vs 26%, 52.9% vs 22.5%, $P < 0.001$) (Table 2).

The change of ODI score in the RF group was significantly higher than that in the control group at the 1st, 3rd, and 6th month (-15.2 vs -10.1 -14.6 vs -8.6, -13.6 vs -7.7, $P < 0.001$), and the proportion of ODI reduction ≥ 15 was also higher than that in the control group at the 3rd and 6th month (45.8% vs 34.1%, 36.4% vs 27.0%, $P < 0.05$) (Table 3).

Table 1. *Baseline characteristics of patients.*

	RF group (n = 135)	Control group (n = 135)	*P* value
Male/Female	55/106	44/65	0.270
Age	71.3 ± 12.5	72.1 ± 14.2	0.371
Disease course (month)	8.2 ± 3.2	9.1 ± 4.1	0.552
<6 months	80	71	
≥6 months	55	64	
Unilateral / bilateral	79/56	81/54	0.126
Disc degeneration	22	19	
Ligament calcification	10	13	
FBSS	31	27	
Radiating pain	47	38	

Values are given as mean ± standard deviation
RF, radiofrequency; FBSS, failed back surgery syndrome

At the 6th month, the excellent rate and efficiency of Macnab in the RF group were significantly better than those in the control group (60.3% vs 36.0%, 81.0% vs 54.1%, *P* < 0.001). During the 6-month follow-up, there were no surgical complications such as infection, bleeding, numbness, nerve injury, or muscle strength weakness in the RF group (Table 4).

Univariate analysis showed that gender, age, pain course, disc degeneration, ligament calcification, lower limb radiating pain, and NRS baseline were not significantly correlated with the excellent and good rate (*P* > 0.05), while FBSS had significant difference (*P* < 0.05). After adjusting for multiple factors, multivariable logistic regression analysis was performed on the above indexes to determine that the independent factor affecting the excellent and good rate was FBSS (*P* < 0.05) (Tables 5-6).

Discussion

The etiology of lumbar facet joint pain in the elderly is related to the following factors: degeneration of the lumbar intervertebral disc, intervertebral height decreased, partial axial stress load transferred to LFJ resulting in excessive load of facet joint, secondary articular cartilage degeneration, and narrowing of joint space and synovitis (13). The lumbar mamilloaccessory ligament is prone to calcification in elderly patients, and the posterior medial branch of the spinal nerve can easily become stuck when passing through it.

Histologic studies have demonstrated that the LFJ is richly innervated with nerve endings. The presence of low threshold, rapidly adapting mechanosensitive neu-

Table 2. *NRS Pain intensity score (primary outcome) among patients and score reduction of 2 or more.*

NRS	RF group (n = 135)	Control group (n = 135)	*P* value
Baseline NRS Mean, SD	5.3 ± 1.8	5.6 ± 1.6	0.772
1-month NRS	n = 134	n = 126	
Mean, SD	3.0 ± 2.0	4.4 ± 2.1	
Mean change from baseline, SD	-2.3 ± 1.1	-1.2 ± 1.2	< 0.001*
3-month NRS	n = 131	n = 123	
Mean, SD	3.3 ± 2.3	4.4 ± 1.9	
Mean change from baseline, SD	-2.0 ± 1.2	-1.2 ± 1.5	< 0.001*
6-month NRS	n = 121	n = 111	
Mean, SD	3.3 ± 2.3	4.5 ± 2.5	
Mean change from baseline, SD	-2.0 ± 1.2	-1.1 ± 1.3	< 0.001*
≥ 2 score reduction (%) at 3-month	80 (61.1)	32 (26.0)	< 0.001*
≥ 2 score reduction (%) at 6-month	64 (52.9)	25 (22.5)	< 0.001*

NRS, numeric rate scale
*Significant differences between the 2 groups

Table 3. *ODI (secondary outcome) among patients and 15 score reduction percentage.*

ODI	RF group (n = 135)	Control group (n = 135)	*P* value
Baseline ODI Mean, SD	39.4 ± 9.1	37.8 ± 8.9	0.576
1-month ODI	n = 134	N = 126	
Mean, SD	24.2 ± 12.3	27.7 ± 13.1	
Mean change from baseline, SD	-15.2 ± 6.7	-10.1 ± 7.4	< 0.001*
3-month ODI	n = 131	n = 123	
Mean, SD	24.8 ± 14.1	29.2 ± 19.4	
Mean change from baseline, SD	-14.6 ± 6.8	-8.6 ± 6.2	< 0.001*
6-month ODI	n = 121	n = 111	
Mean, SD	25.8 ± 10.5	30.1 ± 14.6	
Mean change from baseline, SD	-13.6 ± 8.8	-7.7 ± 9.2	< 0.001*
≥ 15 score reduction (%) at 3-month	60 (45.8)	42 (34.1)	0.024*
≥ 15 score reduction (%) at 6-month	44 (36.4)	30 (27.0)	0.031*

ODI: Oswestry disability index
*Significant differences between the 2 groups

Table 4. *Macnab evaluation of the patients at 6-month.*

Groups	Excellent	Good	Average	Poor	Excellent and good rate (%)	Efficiency (%)
RF group (n = 121)	40	33	25	23	60.3	81.0
Control group (n = 111)	23	17	20	51	36.0	54.1
P value					< 0.001*	< 0.001*

Table 5. *Relationship between baseline characteristics and excellent and good rate at 6-month.*

	Factors	Number	Excellent and good (%)	χ^2	*P* value
Gender	Male	50	33 (66.0)	1.721	0.189
	Female	71	40 (56.3)		
Age	< 70	48	31 (64.6)	1.326	0.202
	≥ 70	73	42 (57.5)		
Disease course	< 6 months	70	45 (64.3)	3.216	0.524
	≥ 6 months	51	38 (74.5)		
Disc degeneration	Yes	22	15 (68.2)	0.553	0.319
	No	99	58 (58.6)		
Ligament calcification	Yes	10	5 (50.0)	0.529	0.719
	No	111	68 (61.3)		
FBSS	Yes	28	8 (28.6)	18.921	< 0.001*
	No	93	65 (69.9)		
Radiating pain	Yes	44	25 (56.8)	1.442	0.392
	No	77	48 (62.3)		

FBSS, failed back surgery syndrome
* Excellent and good rates of FBSS vs non-FBSS in the RF group were statistically different

Table 6. *Multivariate regression.*

Factors	Multivariate regression			
	B value	SE	*P* value	95% CI
Gender	0.581	0.329	0.413	1.125-2.137
Age	0.219	0.116	0.593	0.911-1.249
Pain course	0.822	0.572	0.219	0.258-1.392
Disc degeneration	0.662	0.282	0.477	0.388-2.101
Ligament calcification	0.237	0.731	0.223	0.484-1.303
FBSS	0.610	0.474	0.010*	0.512-1.139
Radiating pain	0.485	0.827	0.439	0.392-2.102
NRS baseline	0.721	0.478	0.637	0.442-1.028

FBSS, failed back surgery syndrome
* The independent factor affecting the excellent and good rate was FBSS

rons suggests transmission of nociceptive information (14). Besides substance P and calcitonin gene-related peptides, a substantial percentage of nerve endings in facet capsules have also been found to contain neuropeptide Y. In degenerative lumbar spinal disorders, inflammatory mediators (15) such as prostaglandins and the inflammatory cytokines interleukin-1, interleukin-6, and tumor necrosis factor have been found in facet joint cartilage and synovial tissue.

In this study, the proportion of LFJ-induced pain in female patients is higher than that in men (171/99), which is mainly related to the thinner articular cartilage thickness in females (16), which makes the joints directly bear stress and prone to degenerate and erode under long-term physiological load. In addition, the decrease in systemic hormone level leads to ligament and capsular laxity, resulting in subluxation of the facet joint and biomechanical instability, which further promotes the degeneration of the facet joint. However, the sample size is too small and needs to be further expanded.

Lumbar facet joint pain is the most common in L4/L5 and L5/S1 facet joints in this study. This suggests that at active sites of segmental motion, facet joint degeneration is more likely to develop.

In this study, 31.5% of patients had lower limb radiating pain due to the continuous release of pain signals from the facet to the spinal cord. There is high convergence of sensory neurons at the synapse of the posterior horn of the spinal cord, resulting in the expansion of the hypersensitive pain sensation in the posterior horn of the spinal cord, that is, central sensitization (17). This radiating pain is more proximal than nerve root radiation pain. Pain emanating from upper facet joints tends to extend into the flank, hip, and upper lateral thigh, whereas pain from the lower facet joints is likely to penetrate deeper into the thigh (8).

Each facet joint receives dual innervation from the medial branches arising from posterior primary rami at the same level and one level above the LFJ. For example, the inferior pole of the L4-L5 facet joint receives innervation from the L4 medial branch, and its superior pole is innervated by the L3 medial branch, which is typically blocked on the transverse processes of L5 and L4. Two points were denervated for the medial branch and facet joint branch. It was confirmed that the pain and movement disorder was significantly improved until 6-month follow-up. It was reported that the effect can be maintained for 12 months or even longer (18-21).

The study further confirmed that the independent factor affecting the excellent and good rate was the FBSS. There was a trend toward patients with FBSS to have a negative outcome after radiofrequency lesion. Age, gender, duration of disease, radiating pain, ligament calcification, disc degeneration, and NRS baseline were not significantly correlated with the excellent and good rate. Multivariable regression analysis also confirms the independent factor affected is FBSS. FBSS mechanism includes both neuropathic pain and nociceptive pain. The causes of the disease are complex, including incomplete removal of protrusions, incomplete decompression, protrusion recurrence, nerve root traction injury, spinal nerve demyelination, scar formation at the operation site, etc., which may require further treatment such as spinal cord electrical stimulation or epidural analgesia.

As for whether RF denervation causes atrophy of the multifidus muscle, MRI imaging shows that there is no morphological change in multifidus muscle volume (22). Radiofrequency neurotomy (RFN) of the medial branches of the spinal dorsal rami is reported in some literature (23). It may be related to excessive RF temperature. In this study, only 75°C thermal coagulation was used. During the 6-month follow-up, no case of muscle strength weakness or denervated afferent hyperalgesia was reported. A larger-scale study is in progress.

There was a significant increase for the expenditures of facet joint interventions, with an overall 53% increase from 2009-2018 in the United States (24). The level of evidence is I to II with moderate to strong strength of recommendation for lumbar diagnostic facet joint nerve blocks by Manchikanti L et al (25). The false-positive rate is 27% to 47% with local anesthetic blocks (26). It may be related to lateral saphenous stenosis or myofascial inflammation. The false positive rate of this study is lower, which is related to the stricter inclusion criteria.

The limitation of this study is that it was only performed in one unit of the National Pain Management and Research Center. It needs to be further carried on in multi-centers in the future.

Conclusions

For the elderly with lumbar facet pain, radiofrequency denervation can effectively reduce the pain and improve the movement disorder. The effect is good until 6 months without any adverse reactions. The independent factor affecting the excellent and good rate is failed back surgery syndrome.

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