



Comparison of the Effectiveness of Radiofrequency Neurotomy and Endoscopic Neurotomy of Lumbar Medial Branch for Facetogenic Chronic Low Back Pain: A Randomized Controlled Trial

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■ **OBJECTIVE:** To compare the effectiveness of radiofrequency neurotomy (RN) and endoscopic neurotomy (EN) of lumbar medial branch (MB) for facetogenic chronic low back pain (FCLBP).

■ **METHODS:** Forty patients with FCLBP were included and randomly assigned to the control group and the experimental group. The control group (20 cases) underwent X-ray-assisted RN and the experimental group (20 cases) underwent EN of the lumbar MB. The patients' Visual Analogue Scale (VAS) score and Oswestry Disability Index (ODI) score were evaluated and compared preoperatively, and at 3 weeks, 6 months, 1 year, and 2 years postoperatively.

■ **RESULTS:** First, the RN group demonstrated successful treatment results ($P < 0.05$) at 3 weeks, 6 months, and 1 year after surgery. At 2 years, patients reported no significant effectiveness ($P > 0.05$). Second, the EN group demonstrated more prolonged successful treatment outcomes compared with the RN group. At 2 years, although the efficacy declined further, the VAS and ODI scores showed significant improvements compared with the preoperative data ($P < 0.05$). Third, there was no difference in VAS and ODI scores between the 2 groups at 3 weeks after surgery ($P > 0.05$). At 6 months and later, the EN group demonstrated better outcomes ($P < 0.05$).

■ **CONCLUSIONS:** For FCLBP, EN and X-ray-assisted RN of lumbar MB are both effective treatments. However, endoscopic lumbar MB neurotomy has the better and longer effectiveness.

INTRODUCTION

The lumbar facet joint (LFJ) has been implicated as one of the causes for low back pain (LBP). LBP that originates from the LFJs and lasts >3 months is considered as facetogenic chronic low back pain (FCLBP).¹ The incidence of FCLBP accounts for 15%–45%² of all types of chronic LBP.

The medial branch (MB) of the lumbar dorsal ramus is the only sensory innervation of the LFJ, therefore, to denervate the MB is the only effective treatment for FCLBP. Because physical examinations and radiography are not specific in the diagnosis, it has been proven that currently the most reliable diagnostic approach for FCLBP is a controlled medial branch block (MBB).^{3,4} Accurately and sufficiently performing lumbar facet neurotomy is the most effective solution.⁵

In 1976, X-ray-assisted percutaneous radiofrequency neurotomy (RN)⁶ was used for FCLBP for the first time. After the MB was located with the assistance of X-ray, a radiofrequency electrode was placed by the MB to damage the nerve with thermocoagulation, so the

Key words

- Endoscopic
- Facetogenic chronic low back pain
- Neurotomy
- Radiofrequency

Abbreviations and Acronyms

- EN: Endoscopic neurotomy
 FBSS: Failed back surgery syndrome
 FCLBP: Facetogenic chronic low back pain
 LBP: Low back pain
 LFJ: Lumbar facet joints
 MB: Medial branch
 MBB: Medial branch block
 ODI: Oswestry Disability Index
 PRR: Pain reduction rate
 RN: Radiofrequency neurotomy
 SPSS: Statistical Package for Social Sciences

STR: Successful treatment rate

VAS: Visual analogue scale

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transmission of pain was intercepted. However, due to insufficient coagulation or other reasons, RN has not yet achieved good long-term effectiveness.⁷ Meanwhile, percutaneous endoscopic technologies have been advancing rapidly for discectomy in recent years.⁸⁻¹⁰ Surgeons can isolate, dissect, coagulate, and sever the MB through a 7-mm incision. Haufe and Mork¹¹ reported significant efficacy of endoscopic facet debridement for the treatment of facet arthritic pain, which confirmed the feasibility of endoscopic denervation for facetogenic pain. In this study, with endoscopic visualization technology, the authors gained a clear view of the MB and the target surgical point to then dissect and completely sever the nerve with thermocoagulation. The aim of this study is to evaluate and compare the effectiveness of RN and endoscopic neurotomy (EN) for the treatment of FCLBP.

MATERIAL AND METHODS

Patients

This study was approved by the ethics committee of the Forth Medical Center of the General Hospital of People's Liberation Army of China, and written forms of consent were obtained from all participants. Between March 2013 and March 2015, patients who were diagnosed with FCLBP and admitted into the Department of Orthopedic Surgery of the Forth Medical Center were screened. After applying the inclusion criteria, 40 patients were included in this randomized controlled trial. The inclusion criteria were: 1) ≥ 3 -month history of chronic LBP; 2) aged between 40 and 70 years; 3) ≥ 3 months of medication or physiotherapy resulting in no improvement; 4) patients retained mechanical LBP, which is elicited by movement of rear

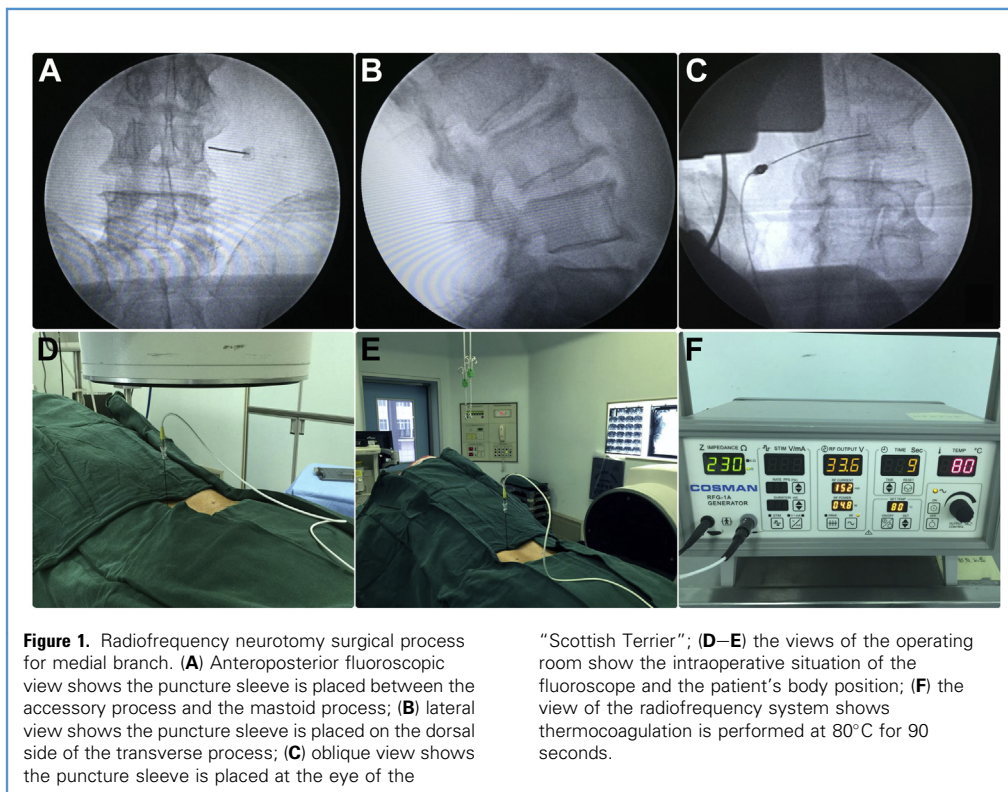
protraction, rotation, and lateral bending of the lumbar spine in a standing position; 5) signs of lumbar vertebral facet joint degeneration on magnetic resonance imaging or computed tomography scans; 6) proliferation or effusion in the articular cavity; 7) patients experienced $>80\%$ pain relief for >1 hour from lidocaine MBB and also $>80\%$ pain relief for >3 hours from bupivacaine MBB. Exclusion criteria were: 1) malignant tumor; 2) mental disorder; 3) previous low back surgery; 4) lumbar vertebral tumor; 5) trauma; 6) infection; 7) congenital deformity; 8) associated neck pain or thoracic pain; 9) lumbar spinal stenosis; 10) neurogenic back or leg pain induced by lumbar disc herniation; 11) pregnancy or lactation; 11) diabetes; 12) severe heart disease; 13) coagulopathy; 14) allergy to anesthesia (e.g., lidocaine, bupivacaine) or contrast agents (e.g., iobitridol).

Forty patients with FCLBP were included and randomly assigned to 2 groups: the RN group (the control group) and the EN group (the experimental group). The sex of patients (13 men and 7 women in the RN group; 11 men and 9 women in the EN group) indicated no statistical difference (χ^2 test, $P > 0.05$); the patients' age, height, weight, duration of pain, number of affected segments, and the preoperative Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) scores showed no statistical difference (t test, $P > 0.05$).

Procedure

The RN group underwent X-ray-assisted percutaneous radiofrequency thermocoagulation to derogate the MB, whereas the EN group underwent percutaneous EN of the MB.

Patients were positioned in a prone position. With the assistance of C-arm X-ray imaging, the target point was discovered to be at the base of the transverse process, between the accessory



process and the mastoid process. Local infiltration anesthesia was administered with 0.5% lidocaine into the skin.

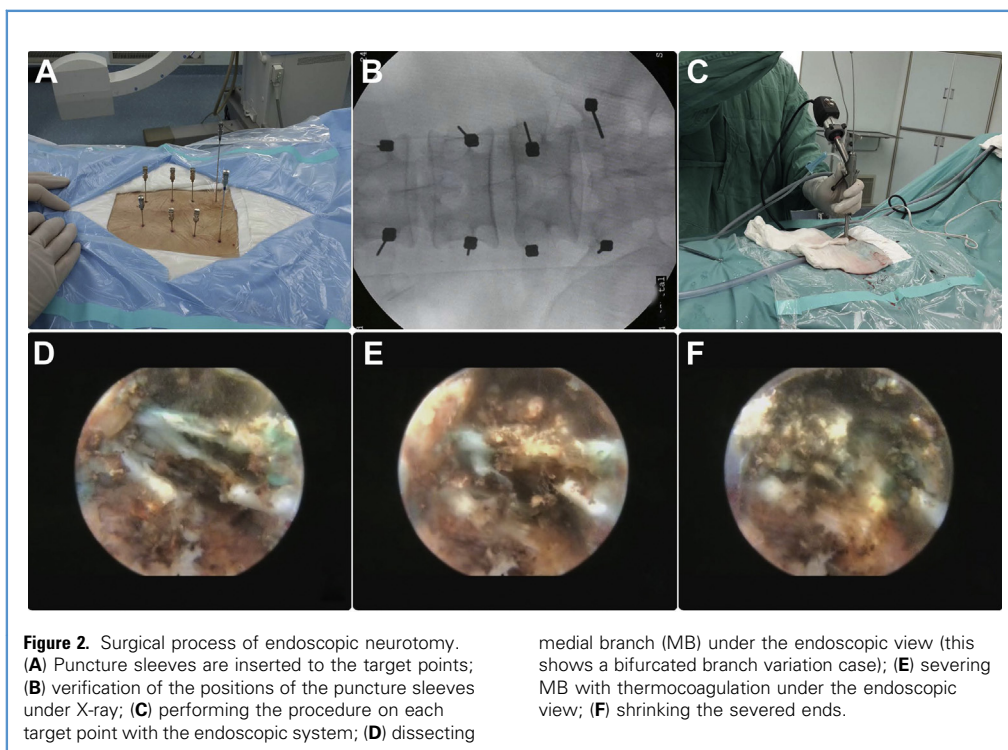
In the RN group, a 20-G radiofrequency puncture sleeve (CC1520-P, Cosman Medical, Inc., Burlington, Massachusetts, USA) was inserted to the target point. After verification under X-ray, 0.5 mL of 1% lidocaine was injected to the target point. The radiofrequency electrode (Cosman) was guided to the target point via the canal in the puncture sleeve. After 30 seconds, the standard radiofrequency thermocoagulation mode was activated. Each cycle of thermocoagulation was performed at 80°C for 90 seconds. Two cycles were performed (Figure 1).

In the EN group, an 18-G puncture sleeve (Hakko corporation, Qianqu City, Nagano Prefecture, Japan) was placed at the target point. After verification under X-ray, 0.5 mL of 1% lidocaine was injected to each target point, followed by the injection of 1 mL mixture of contrast agents (0.8 mL of Omnipaque [Shanghai General Pharmaceutical Co., Ltd, Shanghai, China] mixed with 0.2 mL of methylene blue). When the contrast agents were confirmed to not be in the blood vessel under X-ray, a guiding wire was inserted via the canal in the puncture sleeve, and the sleeve was removed afterward. A 7-mm longitudinal incision was made at the puncture point, and the lumbodorsal fascia underneath was pierced through. A soft tissue dilator and a cannula (VERTEBRIS, Richard Wolf GmbH, Knittlingen, Germany) were navigated into the target point by the guiding wire. The guiding wire and soft tissue dilator were removed thereafter, and the endoscopic spinal system (Wolf) was placed into the target point through the cannula (Figure 2). The endoscopic images were captured from our videotaping device.

Under the endoscopic view, the MB was isolated, dissected, and coagulated by a bipolar radiofrequency dart with a bendable tip (Elliquence, Baldwin, New York, USA). Radiofrequency tissue shrinkage was performed at the severed ends for hemostasis. The endoscopic system and the cannula were then removed. The skin incision was stitched with endothelial suture using 3-0 absorbable thread (Figure 2). This procedure was repeated on each target point. The patients were brought back to the wardroom if they showed no abnormalities 10 minutes after surgery. Patients were administered non-steroidal anti-inflammatory drugs for 3 days orally. After 12 hours of bed rest, patients resumed walking.

Outcome Measurements

The same investigator performed all preoperative and follow-up assessments. This investigator was blinded to the grouping of patients and did not participate in administering any treatment. We use 2 measurements, VAS and ODI scores. Pain intensity was assessed with VAS, which was used to calculate the pain reduction rate (PRR) and the successful treatment rate (STR). VAS is the most important indication of the outcomes. The most obvious reason is that the change of VAS score 100% resulted from the surgical treatments, which makes VAS the core of our study. We focus more on the pain reduction, not only individually but also holistically. Therefore, we defined PRR to quantize the level of pain relief, which was the ratio of the decrease of VAS score to the preoperative VAS score. A successful treatment was defined as $\geq 50\%$ PRR after surgery. The ratio of patients who retained successful treatment in our sample is inevitably one of our main



focuses. We use STR to further demonstrate our results, which means the ratio of the number of patients who retained successful treatment to the total number of patients who underwent the same procedure. The adopted equations were:

$$\text{PRR} = \frac{\text{Preoperative VAS} - \text{Postoperative VAS}}{\text{Preoperative VAS}} \times 100\%$$

$$\text{STR} = \frac{\text{No. of patients with successful treatment}}{20} \times 100\%$$

The severity of disability was assessed with ODI. VAS and ODI results were measured and recorded before surgery and at 3 weeks, 6 months, 1 year, and 2 years after surgery. PRR and STR for each group were calculated. In this study, we do not discuss the correlation between VAS and ODI.

Statistical Analysis

Data were analyzed using IBM Statistical Package for Social Sciences (SPSS) for Windows version 22.0 (IBM Corp., Armonk, New York, USA).

In-Group and Between-Group Analysis

In-group analysis: 1) the postoperative VAS and ODI scores were compared with the preoperative data with a paired sample t test; 2) the postoperative data of VAS and ODI scores at different time points were first analyzed with 1-way analysis of variance, respectively. If the results were not completely the same, further analysis was conducted with the SNK-q method; and 3) the STRs were analyzed with the χ^2 test in pairs.

Between-group analysis: 1) postoperative VAS and ODI scores at different time points were analyzed with a paired sample t test and the Wilcoxon rank-sum test, if necessary; and 2) the STRs of both groups were compared to the χ^2 test.

RESULTS

RN Group Results

The postoperative VAS and ODI scores at 3 weeks, 6 months, and 1 year indicated significant improvement ($P < 0.05$). Data recorded at 2 years showed no significance compared with the preoperative data ($P > 0.05$), showing that the RN group achieved successful treatment results postoperatively, and retained significant effectiveness at 1 year, but no significant effectiveness at 2 years after surgery.

At 6 months, VAS and ODI scores demonstrated significant difference compared with data recorded at 3 weeks ($P < 0.05$). The PRR and STR decreased from $63.04 \pm 12.49\%$ and 90% at 3 weeks to $45.68 \pm 13.18\%$ and 60% at 6 months. The effectiveness at 6 months decreased significantly.

At 1 year, VAS and ODI scores demonstrated significant difference compared with data recorded at 6 months ($P < 0.05$). The PRR and STR decreased from $45.68 \pm 13.18\%$ and 60% at 6 months to $21.61 \pm 13.33\%$ and 0.00% at 1 year. The effectiveness at 1 year decreased drastically.

At 2 years, VAS and ODI scores demonstrated significant difference compared with data recorded at all previous time points postoperatively ($P < 0.05$), but no significant difference compared

with the preoperative data ($P > 0.05$). The RN group retained no effectiveness at 2 years after surgery.

The RN group gained successful treatment postoperatively, however, the effectiveness declined significantly at 6 months, and the STR further declined to 0.00% at 1 year drastically. At 2 years, no significant effectiveness was reported.

EN Group Results

Compared with the preoperative data, the postoperative VAS and ODI scores at 3 weeks, 6 months, 1 year, 2 years indicated significant improvement ($P < 0.05$). The PRR and STR declined but remained at $44.17 \pm 11.33\%$ and 45% at 2 years. The EN group showed significant postoperative effectiveness in the 2-year follow up.

VAS and ODI scores recorded at 3 weeks and at 6 months demonstrated no significant difference ($P > 0.05$) compared with the data recorded at 6 months, VAS and ODI scores recorded at 1 year showed significant difference ($P < 0.05$), but STR (80%) at 1 year indicated no difference from STR (90%) at 6 months ($P > 0.05$). The effectiveness began to decline at 1 year after surgery, but the insignificant change of STR suggested the effectiveness at 1 year was still good.

At 2 years, VAS, ODI, PRR, and STR were all significant compared with previously recorded data ($P < 0.05$). The effectiveness in the EN group declined significantly at 2 years, but the STR remained at 45% .

The effectiveness in the EN group started to decline at 1 year after surgery but the STR (80%) remained high. At 2 years, the effectiveness further declined, causing the decrease of STR, however, it still demonstrated significant improvement compared with the preoperative data. Therefore, the EN group achieved good long-term effectiveness (Table 1, Figure 3).

Between-Group Analysis

At 3 weeks after surgery, both groups showed significant improvement in all measured aspects ($P < 0.05$). However, the effectiveness of treatment was significantly better in the EN group at 6 months, 1 year, and 2 years after surgery than those of the RN group ($P < 0.05$).

Complications and Anatomic Variations

All patients recovered without infection or other complications. Among all 136 surgical points, we uncovered 14 target points with anatomic variations, including 11 bifurcated branches and 3 trifurcated branches. The variation rate is 10.3% .

DISCUSSION

It has been proven that until now the most reliable diagnostic method for FCLBP is controlled MBB,^{3,4} considering that symptoms and radiography are not specific in the diagnosis. Controlled MBB is performed with 2 different local anesthetic drugs that have different durations of effect (e.g., lidocaine and bupivacaine) to block the source of pain or the transmission. If the patient sustains pain relief that lasts for the same duration as the efficacy of the drugs, they are considered to have a positive reaction to controlled MBB. Therefore, the diagnosis can be FCLBP. MBB with percutaneous RN has been the only evidence-based effective treatment⁵ for FCLBP. It is to damage

Table 1. Preoperative and Postoperative Visual Analogue Scale, Pain Reduction Rate (%), and Oswestry Disability Index

| Indicators | Preoperative | 3 weeks Postoperative | 6 months Postoperative | 1 year Postoperative | 2 year Postoperative |
|------------|--------------|-----------------------|------------------------|----------------------|----------------------|
| VAS | | | | | |
| RN group | 7.15 ± 0.81 | 2.60 ± 0.75* | 3.85 ± 0.88*† | 5.55 ± 0.83†‡ | 6.85 ± 0.81†‡§ |
| EN group | 7.15 ± 0.88 | 2.30 ± 0.66* | 3.15 ± 0.57*† | 3.40 ± 0.68*† | 3.93 ± 0.75*† |
| PRR (%) | | | | | |
| RN group | | 63.04 ± 12.49 | 45.68 ± 13.18† | 21.61 ± 13.33†‡ | 3.39 ± 13.43†‡§ |
| EN group | | 67.50 ± 9.63 | 55.45 ± 9.01† | 51.49 ± 12.83† | 44.17 ± 11.33† |
| ODI | | | | | |
| RN group | 76.75 ± 7.07 | 28.00 ± 3.84* | 32.5 ± 4.44*† | 50.8 ± 7.77*†‡ | 78.5 ± 5.80†‡§ |
| EN group | 76.3 ± 0.66 | 26.10 ± 3.34* | 27.5 ± 2.96*† | 35.7 ± 5.81*† | 44.35 ± 3.99*†§ |

VAS, visual analogue scale; RN, radiofrequency neurotomy; EN, endoscopic neurotomy; PRR, pain reduction rate; ODI, Oswestry Disability Index.

*Compared with preoperative data, the difference is significant.

†Compared with data recorded at 3 weeks after surgery, the difference is significant.

‡Compared with data at 6 months after surgery, the difference is significant.

§Compared with data at 1 year after surgery, the difference is significant.

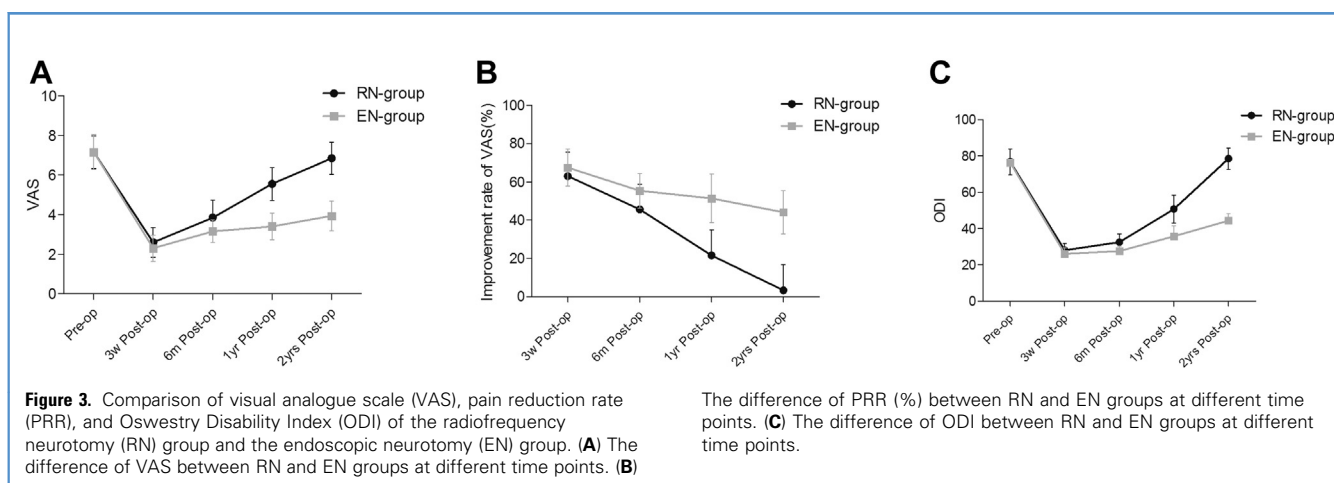
the MB with thermocoagulation at 80°C, which is created by percutaneously placed RF electrodes, so the transmission of pain from the LFJ is intercepted. This technique has been widely used clinically for pain reduction.¹²⁻¹⁴ For patients with positive reaction to controlled MBB, RN demonstrates laudable effectiveness,¹⁵ but the long-term effectiveness has not been proven good enough.

Some researchers¹⁶ have concluded that RN showed no significant improvement compared to the placebo group. A systematic review based on 16 articles⁷ states that the effectiveness of RN lasts only 7–9 months. In our study, the outcomes indicated RN remained effective for over 12 months, but the PRR was only 21.61 ± 13.33%, and STR declined to 0.00% at 12 months. At 2 years after surgery, our data suggested no more effectiveness. Another recent systematic review¹⁷ that summarized the outcomes of 4 randomized control trials with an average follow-up of 3–6 months suggests there is not enough evidence to entirely affirm the effectiveness of RN.

The unsatisfactory long-term effectiveness of RN may be the result from 3 shortcomings of this procedure. First, the scope of effective thermocoagulation is an oblate spheroid with a maximum diameter of 2 mm¹⁸ through the axis of the electrode. Therefore, the thermocoagulation scope covers less tissues in the direction of the needle, causing insufficient damage to the target nerve and incomplete derogation.

In addition, percutaneous puncture is performed under blind-sight. The surgeon is not able to observe whether the electrode and the nerve are in contact but can only guide the electrode to the target point by observing the bony structures with the assistance from X-ray. Even if the electrode reaches the target bony point, a good contact with the MB cannot be guaranteed for all patients due to possible anatomic variations. Therefore, effective thermocoagulation cannot always be achieved.

Furthermore, with respect to the effectiveness of nerve damage, RN merely coagulates the target nerve, instead of physical



severance. The nerve fibers can restore the pain transmission pathway after their regrowth along the remnant from the nerve sheath. Pain will recur at 6 months to 1 year after surgery.⁷

These 3 causes for poor long-term effectiveness—an insufficient coagulation scope, the blindsight combined with possible anatomic variations, and regrowth of nerve fiber via remnant—are inevitable with RN technology itself, independent of the surgeon's experience and skill level.

One approach to improve the effectiveness of RN is to change the direction of the electrode from a perpendicular position to a parallel position to the nerve,^{19,20} to enlarge the scope of coagulation. Moreover, because blindsight of the target surgical point causes inaccuracy of the electrode placement, some surgeons²¹⁻²³ use computed tomography or a 3-dimensional navigation system when locating the target point to place the electrode more accurately. To further increase the effectiveness, one more attempt to improve the accuracy of puncture is with surface electromyography, which can provide a reference for the contact between the electrode and the nerve, to retain better coagulation. Some researchers have reported better results after adopting one or more of the methods mentioned earlier, however, the outcomes cannot always be reproduced. Therefore, these approaches are not recognized to be efficient in improving the effectiveness of RN. Consequently, the effectiveness of RN remains insufficient.

Endoscopic technology enables surgeons to release the nerve root inside the spinal canal, dissect intervertebral disc, or perform spinal canaloplasty and many more meticulous operations through a 7-mm incision.⁸⁻¹⁰ The Haufe and Mork¹¹ report proved the feasibility of using an endoscopic system for surgeries on facet joints, another retrospective study²⁴ on the effectiveness of EN for FCLBP also verified the safety and effectiveness of EN.

In this study, the results indicate significant better long-term effectiveness in the EN group than that of the RN group, and an incidental anatomic variation rate of 10.3% was observed with the assistance of the endoscope in the EN group, whereas such possible variations stay uncovered in the RN group. Because EN is performed under endoscopic view, the endoscopic system helps to not only accurately locate the target nerve, even with anatomic variations, but also results in a complete physical severance of the MB. The bipolar radiofrequency dart can also coagulate and shrink the severed ends to minimize the chance for nerve regeneration. EN does not encounter the 3 causes for unsatisfactory long-term effectiveness that RN fails to resolve and achieves significantly better outcomes and long-term effectiveness.

However, although the nerve is effectively severed, the result of this study still found the recurrence of LBP in the EN group. We suppose there could be 2 explanations. The first is that nerve regeneration still occurs, even if the nerve has been effectively severed, but the regeneration seems harder in the EN group than that in the RN group because of the more effective severing. The second is that the recurrent pain originates from not only the facet joint, but also the intervertebral disc or lumbar muscles or ligaments. Smuck et al.²⁵ has also reported a quantitative radiologic study that demonstrated a significantly greater amount of disc degeneration after lumbar MB RN, which could cause discogenic or neuropathic pain. Therefore, the recurrence of LBP might not be caused by the facet joint any more.

During the process of EN, the procedure is carried out under lysis of 0.9% saline solution and the bipolar radiofrequency dart's local temperature stays under 42°C. Compared to RN, EN can maintain a lower temperature apart from physically severing the MB. Thanks to these advantages, EN can be used for a wider range of indications such as failed back surgery syndrome (FBSS).

FBSS describes the situation in which the pain remains or recurs shortly after surgery. It is reported that the prevalence of facet joint pain is 7%²⁶ to 16%²⁷ in patients with FBSS. Researchers reported these patients with FBSS with facet joint pain who have been treated with RN can retain an STR of 58.8%.²⁶ However, it can cause high risk in some cases, in which unwanted high temperature of the never root might occur. The RF generator can create a 250–500 KHz alternating electromagnetic field through the RF electrode. This electromagnetic field can induce the ions in the tissues to vibrate and the molecules to keep rubbing, and thus, heat is created in this field. If the patient has received metal implants previously, such as pedicle screws, considering that the ideal locations for RF electrodes are close to the positions of pedicle screws, and the percutaneous puncture is performed under blindsight, the surgeon is not able to observe whether the electrodes and the pedicle screws are in contact. If they are, the pedicle screws will be heated up and the total heated area will be much larger than what the procedure is intended for. This situation is very dangerous.²⁸ However, during EN, the metal implants can be located accurately under endoscopic view, and the bipolar radiofrequency dart's local temperature stays under 42°C, or even lower with the lavage of 0.9% saline solution. This feature of the endoscopic system can avoid the risk of over-heated area that RN cannot resolve. Therefore, EN is safer than RN in the treatment for FCLBP with metal implants, especially for the FBSS.

Inevitably, EN requires a 7-mm incision for each target point. Although the iatrogenic injury is bigger than that of RN, the incisions are so small that EN does not cause more pain or higher risk of complications significantly. In this study, all patients gained proper healing of wounds without infection from the incision, or any other complications.

Limitations

In accordance with the principles of patient's informed consent, this study is not double-blinded. This might affect the accuracy of results to some extent. In addition, this study cannot exclude the influence of physiotherapy or medication that the patients received at their own discretion. Further, because of the scope of this study, the authors did not test or evaluate the function of the lumbar spine with precision. Moreover, this study is limited to a sample of 40 patients who were treated in the same facility. In future studies, a multicenter trial with a larger sample will help ensure better representativeness and higher accuracy of the conclusions.

CONCLUSIONS

EN and X-ray-assisted RN of lumbar MB are both effective treatments for FCLBP. However, endoscopic lumbar MB neurotomy has the advantage of higher surgical precision, better safety, and longer effectiveness.

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