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The Efficacy of Selective Nerve Root Injection Guided by Ultrasound or Fluoroscopy in Patients with Chronic Low Back Pain and Unilateral Radiculopathy

Mei Zhang[1], Zhonghuang Xu[2], Zhiyou Peng[3], Bolun Su[4] and Yizhun Zhu[1]*

[1]State Key Laboratory of Quality Research in Chinese Medicine, School of Pharmacy, Macau University of Science and Technology, China

[2]Department of Pain Medicine, Arion Cancer Center, China

[3]Department of Pain Medicine, The First Affiliated Hospital, College of Medicine, Zhejiang University, China

[4]School of Medicine, Macau University of Science and Technology, China

Abstract

Purpose: The purpose of this study is to evaluate the efficacy of ultrasound-guided or fluoroscopy-guided selective nerve root injection in patients with chronic low back pain and unilateral radiculopathy (caused by Lumbar Disc Herniation or Spinal Stenosis, shorthand for LDH or SST).

Methods: 79 patients with chronic low back pain combined with radiculopathy were selected and divided into ultrasound group and fluoroscopy group. Local anesthesia and steroid infiltration were performed with ultrasound guidance or fluoroscopy guidance respectively around the marked nerve roots. We observed the time it took for the needle to reach the target nerve root during treatment. Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) were collected before operation and one, two and three months after operation.

Results: Needle placement takes 220.3 ± 8.9 s in the ultrasound group, and it takes 445.8 ± 27.2 s in the fluoroscopy group. VAS scores and ODI (clinical improvement) were significantly decreased at each time point.

Conclusion: Selective nerve root injection under the guidance of both techniques showed significant clinical efficacy (VAS score and ODI decreased). Ultrasound guidance is a safe alternative that can greatly reduce the time it takes for the needle to reach the target nerve root. However, there is little difference in the effect between the two guidance methods. As far as clinical practicality is concerned, ultrasound is still superior to fluoroscopic guidance for its convenience and non-radiation.

Keywords: Disability assessment; Fluoroscopy; Ultrasound; Lumbar nerve root

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Correspondence:
Mei Zhang, State Key Laboratory of Quality Research in Chinese Medicine, School of Pharmacy, Macau University of Science and Technology, Macau, China, Tel: 65586565; E-mail: meizhang@must.edu.mo

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Introduction

Low Back Pain (LBP) is one of the leading causes of disability worldwide. It is highly prevalent and is associated with pain, functional impairment, long-term incapacity, work absenteeism and high utilization of healthcare [1,2]. Over the years, at the suggestion of "The Current Practice Guidelines for Chronic Pain Management", nerve root injection was used in the treatment of waist and leg pain and radioactive pain [3]. Good curative effects have been achieved [4]. It is a target-specific technique that aims to deliver a small amount of a high concentration of local anesthetic and steroid to the site of documented pathology [5]. Fluoroscopy (FL) interventions have been used preferentially in injection therapy. However, fluoroscopy has several disadvantages, including radiation exposure, high-cost equipment housed in specialized facilities, and the necessity for a radiologist's assistance [6]. In contrast, ultrasound (shorthand for US) involves no radiation exposure, relatively low cost and more widely available. However, due to its short development period, there are very few researches on ultrasound-guided injection therapy.

Therefore, the current study was designed to evaluate the efficacy of ultrasound-guided nerve root steroid injection compared with fluoroscopically guided injections for patients with lower back pain and unilateral radiculopathy.

Methods

This study is a prospective comparative study. All the patients' privacy and data were maintained confidentially throughout the research process. No direct contact with the study population was included in this study, and all patient identifiers were removed from the data set on initial collection. Approval from the Institutional Review Board of The University Hospital, Macau University of Science and Technology was obtained, including a written informed consent. Between February 2017 to March 2019, 189 patients with unilateral lower lumbar radicular pain due to spinal canal stenosis or herniated disc were referred to our pain clinic. Diagnosis of unilateral lower lumbar radicular pain was based on the clinical pain profiles, physical examinations, and CT or MRI. The clinical pain profiles mean lancinating pain, which travel along the lower limb and spread in a band no more than 2 to 3 inches wide. The EMG test was used to rule out other diseases such as other peripheral neuropathy, progressive motor deficit or significant sensory deficit, and Cauda equina syndrome, and so on. Those 123 patients who met the following inclusion criteria were selected: Aged 18 or older, agree to receive ultrasound or fluoroscopy guided selective nerve root injection. Further inclusion criteria included patients who had experienced chronic radicular pain for at least 3 months and had failed to respond to anti-inflammatory medications, analgesics or physical therapy of at least 4 weeks. Finally, 79 eligible patients were selected. Patients with sacroiliac joint or facet joint pain based on clinical or radiological evaluations, psychiatric disorders, bleeding disorders, infection signs, inflammatory diseases, or rheumatoid disorders were excluded in this study. Patients who have had previous lumbar surgery, progressive motor deficit or significant sensory deficit, Cauda equina syndrome were also excluded. We only permitted acetaminophen and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) for the pain control. Patients were assigned according to a computerized randomization list to either an ultrasound-guided group or a fluoroscopy-guided lumbar selective nerve root injections group. All patients were placed in the prone position on a radiology table with a pillow under the hip, under appropriate monitoring with intravenous access and with sedation as required. All patients received lumbar selective nerve root injection either between L4 and L5 or at a higher level based on clinical and radiological manifestations. If the injection resulted in significant pain relief, the second and third injections were performed using the same technique as the first. All injections were performed by an investigator experienced in ultrasound and fluoroscopy techniques. Outcome evaluators and data analysts are not aware of the plan as patients and investigators do. All the injection procedures were performed in an operating room setting.

Ultrasound-guided technology

It was performed using the method described by Loizides et al. [7]. A needle (22 G) was inserted approximately 45 degrees into the skin using the in-plane technique. After confirming no inhalation, a mixture of 5 mL of 0.3% lidocaine and 7 mg betamethasone was injected.

Fluoroscopic localizing

Under the guidance of C-arm, front, back and side perspectives, the image intensifier is placed above the patient, which makes the X-ray project at an angle of about 45° to display the "Scottish dog" image. Rotating the C-shaped arm until the injected nerve root and the front of the upper articular process of the same vertebra ("Scottish dog" ear) are located at the midpoint of the posterior edge of the upper endplate of the vertebra. The nerve root normally runs a few millimeters below the pedicle ("Scottish dog" eye) and 1 to 2 mm above the vertebral body, where is the puncture point. The puncture needle is slightly inserted into the outer side of the pedicle, until it reaches the vertebra. If pain is not inflicted in the nerve root, the puncture of the needle is adjusted a few millimeters outwards until the patient can sense the pain. Then inject 0.5 ml to 1.0 ml of contrast medium to confirm whether the needle tip is located in the nerve root sheath. The contrast medium should be injected slowly into the nerve root sheath. Both groups of patients noticed the time it took from the start of the procedure to the correct placement of the needle.

Criteria

Clinical efficacy: 1. Pain relief, mainly depends on VAS score (VAS for pain from 0 to 10, where 0 is no pain and 10 is the worst pain imaginable); 2. The ODI, a multipurpose questionnaire of 10 items used to assess functional health status and well-being of adults [8]. Each parameter is evaluated on a six-point scale (0–5). During pre-procedural evaluation of every patient, the ODI score was determined (baseline ODI) and again the ODI score was evaluated after the procedure, at the end of 1st, 2nd, 3rd month. The point in each section that best describes the patient's problem was noted. The sum of these scores from 10 sections constituted the 'point-total'. This 'point-total' divided by '50' and multiplied by '100' = percent disability (ODI score). B. Compare the timeliness of the two groups of draping to correct placement of needle was noted. C. Safety (occurrence of adverse events). We checked for immediate adverse events such as vasovagal reaction, facial flushing, or severe back pain within a few minutes after the injection. Patients were monitored for 4 h and subsequently discharged with the advice to attend our pain clinic next week. In the pain clinic, they were followed up for 3 months. VAS scores and ODI values were noted at the end of 1st, 2nd, and 3rd month. In both groups, patients received 2 consecutive injections 2 weeks apart. The second injection proceeded conditionally. If the initial injection resulted in significant symptom reduction (VAS ≥ 50%), the second and the third injection will follow the first injection method. If no pain relief or pain deterioration was observed, the second or third injection was not considered and re-evaluation would repeat. If the patients experienced pain relief of <50% reduction in VAS, a second injection was scheduled.

Statistical methods

All data were entered into an excel sheet and analyzed using Statistical Package for Social Sciences version 20 [IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.]. The continuous data were expressed as mean ± standard deviation and were analyzed using independent samples t-test except for intragroup analysis which was analyzed using paired t-test. Categorical data were expressed as number of patients (n) and analyzed using Chi-square test. $P<0.05$ was considered significant.

Results

The qualifications of 123 patients were evaluated, and 79 patients were randomized. Among the injection protocols that we could not complete, there were 30 cases of violation of the protocol due to acute disc herniation, osteoporotic fractures, and participation in other injections and in 14 cases due to surgery after giving up follow-up contact, data was lost. 90% of patients received three consecutive injections. The patient's basic physical condition and initial condition are not statistically different (Table 1). After 1, 2 and 3 months of follow-up, the VAS and ODI's score of the ultrasound guided

Table 1: The basic physical condition and initial condition of 79 patients after three consecutive injections.

Project/Group	U group (n=41)	F group (n=38)	*P*
Age (year)	55.2 ± 8.1	57.0 ± 6.5	0.735
Height (cm)	162.8 ± 6.9	165.58 ± 5.3	0.662
Weight (kg)	62.6 ± 8.6	63.8 ± 8.0	0.704
BMI	22.8 ± 2.0	22.2 ± 2.5	0.459
Sex: Male	18 (43.9%)	14 (36.8%)	
Female	23 (56.1%)	24 (63.2%)	0.847
Affected side: left	24 (58.5%)	25 (65.8%)	
right	17 (41.5%)	13 (34.2%)	0.512
Pain duration (month):	9.7 ± 6.0	9.6 ± 5.	0.491
Number of shots: 1	41 (100%)	38 (100%)	
2	38 (92.7%)	36 (94.7%)	
3	37 (90.2%)	35 (92.1%)	0.729
Diagnosis: LDH	20 (48.8%)	18 (47.3%)	
SST	21 (51.2%)	20 (52.6%)	0.864
Target nerve root: L4	13 (31.7%)	11 (29.0%)	
L5	28 (68.3%)	27 (71.1%)	0.922

U group: Ultrasound group; F group: Fluoroscopy group

group and the X-ray fluoroscopic guided group were significantly decreased compared with those before treatment, and the difference was statistically significant. But group to group comparison between Ultrasound guided group and the X-ray fluoroscopic guided group was not statistically significant (P<0.05, Table 2). Compared with the X-ray fluoroscopy group, the time when the puncture needle was placed in the target nerve root in the ultrasound-guided group was significantly reduced, and that in the U group (220.3 ± 8.9s) < in the F group (445.8 ± 27.2s) P<0.001, which was statistically significant. In addition, there was no significant difference between the two groups in the number of attempts and the length of needles, (P>0.05, Table 3).

Discussion

Recently, ultrasound-guided nerve root blocks and transforaminal injections have been well established and procedural feasibility studies have been reported [6,7]. In the "Diagnosis and Treatment of Lumbar Disc Herniation Accompanied By Radiculopathy" (2013 Edition), NASS evidence-based clinical guide", a global professional authority of spine, clearly points out that in most cases, selective nerve root injection of glucocorticoid can relieve pain and reduce inflammation of compressed nerve roots and surrounding tissue. Some patients can achieve long-term pain control, which can be used as the first treatment (recommendation level B, evidence level 2b) [8]. In view of the guidance of this guideline, we found that the success rate of single injection of lumbar nerve roots in the treatment

Table 3: Comparison of the time when the puncture needle reaches the target nerve root under fluoroscopy guidance and ultrasound guidance.

Project/Group	U group (n=41)	Group F (n=38)	*P*
Duration of procedure (s)	220.3 ± 8.9	445.8 ± 27.2	<0.001
Number of needle insertion attempts	0 (0-1)	0 (0-1)	NS
Number of needle passes (cm)	5 (4-8)	5 (3-6)	NS

of patients with unilateral chronic low back pain was more than 50% (based on preoperative and postoperative VAS scores). There were no related complications or death events in this process. It can be said that peri-radicular injection is a safe procedure, which can alleviate the radicular pain in a large number of patients. The value of this procedure can be further elucidated in the future through further study of longer-term follow-ups.

The results of our study showed that there was no significant difference in VAS evaluation between US guided group and FL guided group. This indicates that, in both approaches, the medication is able to reach the peri-radicular space. However, the long-term pain-relieving effect still needs further investigation. Ultrasound offers the advantages of bearing no radiation exposure, more widespread availability and the possibility of performance in most inpatient and outpatient settings [9]. Furthermore, at the target point, the rate of aberrant analgesia spread (Para foraminal, epidural, or intravascular) in the US-guided method was comparable to fluoroscopic-guided methods [10]. Other studies evaluated a combined US and fluoroscopy-guided method with a success rate of 90% to 95% and a very low rate of intravascular spread, which translated into a good clinical response with effective and fast decreases in pain [7]. Another study compared the results of two groups of patients undergoing either US guided (followed by CT confirmation of accuracy) or CT-guided blocks. The needle tip accuracy and pain relief efficacy in the US-guided group was comparable to the CT-guided group, while the former was superior in terms of procedural time (nearly half) and mean radiation doses [11]. One more study has also confirmed comparable results in terms of treatment outcome, while US-guided blocks were associated with shorter performance times. This is also consistent with our findings in this study; the performance time was significantly quicker with US than with FL. This may have occurred as a result of 2 reasons. Firstly, fluoroscopic imaging requires Anteroposterior (AP), lateral, and oblique views for the appropriate placement of the needle, which is a critical step for safe needle placement and for the correct identification of the target lesion [12]. This can be time-consuming. Moreover, the procedure involved in intermittent FL requires an ample time. Lengthier performance times to allow for the injection of contrast were required. In contrast, US allowed for the visualization of the contours of the root of the SAP, which were immediately identifiable in short- or long-axis view and were less affected by the patient's position [13]. Furthermore, the procedure was quicker because the injection was performed under real-time

Table 2: Comparison of VAS and ODI scores of ultrasound-guided group and fluoroscopy guided group after three months of follow-up with those before treatment.

Project/Time		VAS U group	VAS F group	P	ODI U group	ODI F group	*P*
Baseline		6.61 ± 1.22	6.24 ± 0.93	>0.05	61.73 ± 6.86	60.24 ± 5.14	>0.05
After	1 month	3.32 ± 1.51	3.05 ± 1.02	>0.05	33.20 ± 6.00	34.73 ± 6.08	>0.05
	2 months	2.88 ± 0.62	3.00 ± 0.71	>0.05	34.56 ± 4.03	33.21 ± 4.65	>0.05
	3 months	3.76 ± 0.64	3.14 ± 0.88	>0.05	32.87 ± 4.35	32.10 ± 5.89	>0.05
P		<0.05	<0.05		<0.05	<0.05	

U group: Ultrasound group; F group: Fluoroscopy group

US showing the needle. Therefore, we believe that ultrasound-guided selective nerve root injection therapy is more convenient, more time-saving and safer in clinical application in patients with chronic low back pain accompanied by unilateral neuralgia. Some adverse events have been reported in the literature, such as accidental intravascular injections, hematomas, dural punctures, and nerve damages. We did not encounter any adverse events, and further observations involving larger samples are helpful. Our study, however, has some major limitations. First, the study number is low. The minimal sample size hinders us from showing statistical differences for some factors including blockage level and type. Likewise, based on selections, our results cannot be generalized to other patient groups (obese patients, those with spine deformities including scoliosis, failed back surgery patients, etc.). The BMI of the patients included in this study was relatively low, and ultrasound may not have provided good images of these obese patients. Third, it was not checked by fluoroscopy guided whether the injectate was properly injected into the targeted area in ultrasound-guided or not. This way may have effects on the result. Finally, as all studies focusing on pain as the major outcome, confounding factors and sources of bias cannot easily be controlled and excluded (lack of objective measures, patients' psychology, occupation, and litigation components and demands).

Conclusion

Selective nerve root injection is effective in treating patients with chronic low back pain and unilateral radicular pain. Compared with fluoroscopy guided injections, ultrasound-guided did not show significant differences in pain reduction and improved functional outcomes. However, ultrasound-guided greatly reduced the overall surgical procedure time and avoided the associated radiation exposure risks. Therefore, ultrasound-guided selective nerve root injection is worthy of popularization in patients with chronic low back pain combined with unilateral radicular pain.

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