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Ultrasound versus Fluoroscopy Guided Caudal epidural Pulsed Radiofrequency for Peripheral Neuropathy

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ABSTRACT

Radiation safety of fluoroscopy is gold standard for chronic pain interventions but radiation exposure risk is still the main issue with its use. The aim of this study was to compare the efficacy of ultrasound-guided caudal pulsed radiofrequency (USCPRF) with fluoroscopy guided caudal pulsed radiofrequency (FCPRF) for patients with peripheral neuropathy (PNP). A caudal pulsed radiofrequency (CPRF) for 56 patients with PNP and randomly assigned to either the ultrasound (US) -guided or the fluoroscopy (FL) -guided group. The pain evaluate was measured by patients' ratings of a 10-point numerical pain scale (NPS) before and 2 days, 30 days, and 120 days after treatments. The blocking procedures were well tolerated, and comparable pain relieving effects appeared. The pain intensity, as measured by NPS, significantly decreased at 2 days, 30 days and 120 days after CPRF in both US and FL groups, respectively, compared with that of baseline ($P < 0.05$). There was same result in in both approach, US-guided and FL-guided. Ultrasonography can be an alternative method for its convenience and efficacy in CPRF for PNP patients, with shorting time and no exposed to radiation.

Keywords: caudal pulsed radiofrequency, fluoroscopy, pain scale, cannula, bonferroni.

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1. INTRODUCTION

Peripheral neuropathy is a general term describing disease affecting the peripheral nerves, meaning nerves beyond the brain and spinal cord. Peripheral neuropathy can result from traumatic injuries, infections, metabolic problems, inherited causes, and exposure to toxins. One of the most common causes is diabetes. [1-3] People with peripheral neuropathy generally describe the pain as stabbing, burning, or tingling in hands and feet. Treatment strategies for PNP are wide and varied, such as medication, physical therapy, acupuncture, manipulation, transcutaneous electrical nerve stimulation, pulsed radiofrequency, injections, and surgery [4-7]. There is an ongoing need for evidences of long-term effect and high-quality randomized controlled trial investigations for these strategies.

The pulsed radiofrequency (PRF) technology, which was recently invented (Sluijter performed the first PRF lesion in February of 1996), is frequently utilized to relieve long-term discomfort. Although the technique of PRF's pain-relieving function has not been well investigated, the electrical field created by it has been suggested to be responsible for its therapeutic effect. PRF is delivered in short (20msec) bursts twice per second, followed by a quiet phase (lasting 480msec) in which no current is applied. Short activation followed by a long rest period to expose target neurons and structures to an electric field without causing major structural failure. [8-13]. Because of its low tissue damage, PRF has been quickly embraced in medical care to cure a number of diseases or disorders, including neuralgia, joint stiffness, and muscular pain [15-16].

The objective of this study was to evaluate the efficacy of UCPRF for patients with PNP in comparison with FCPRF through a prospective, randomized, single-blind clinical trial.

2. MATERIALS AND METHODS

There were 56 patients participated in this randomized, single-blind study. They were enrolled and then randomly assigned into two groups according to a random number table and underwent US guided (US, n = 28) or FL guided (FL, n = 28) CPRF, respectively, in the functional neurosurgical center of Almmosay Hospital from January 2020 to July 2022. The study was approved by our university, and all patients gave informed consent before this study. The patients had experienced screening that included medical history and physical examination, followed by nerve conduction study and MRI of the spine. All patients were diagnosed with PNP depend on clinical evaluation and nerve conduction study. Inclusion criteria (1) > 6-month history of persistent pain, paresthesia or tingling in one or both legs and feet (2) > 4 pain score in NRS (3) Unsatisfactory response to conventional treatments, including physical therapy or medications. Exclusion criteria (1) Myopathy (2) Psychiatric disorders (3) Infection at the needle entry site; (4) Bleeding or coagulation disorders.

2.1. US-Guided CPRF Procedures.

The patients were placed in prone position. (Sonosite, USA) US machine, equipped with a multifrequency linear probe 4–13MHz was used. The skin was prepared with Betadine and draped in the usual sterile fashion at the region of injection (see Fig.1). The US probe was also sterilized with Betadine. There are two planes to insert the needle in ultrasasonic gaude, inplane and outplane [16-17].

A cutaneous and subcutaneous anesthesia with 3 ml of 2% lidocaine, a 22- gauge 3.5-inch RF cannula with 20 mm (SMK pole needle, 150 mm with a 20 mm active tip; Cotop International BV, Amsterdam, Netherlands) active tip into the epidural space through the sacral hiatus.

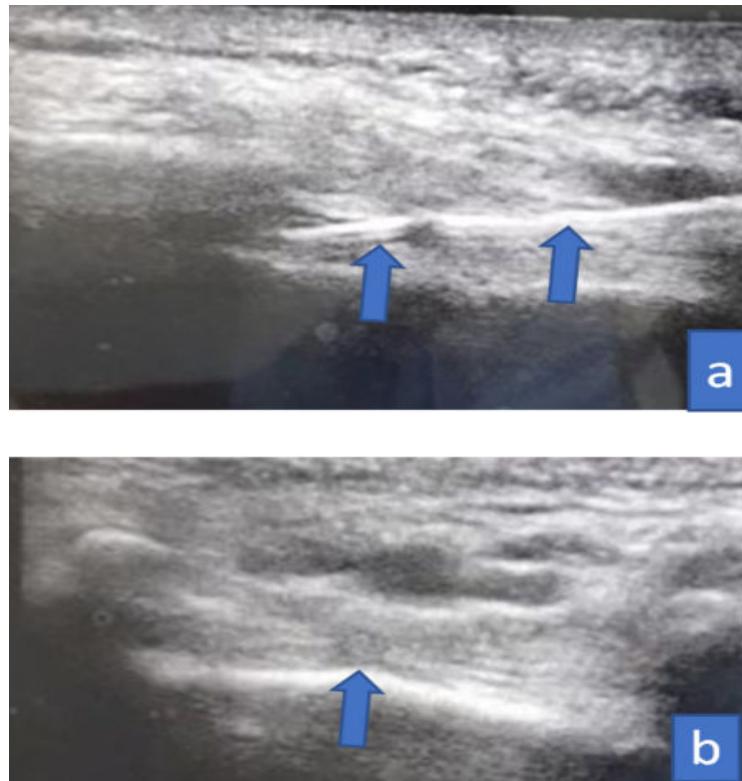


Figure 1. Ultrasound guide CPRF In-plane (a) and out-of-plane (b) blue arrow RF needle.

2.2. FL-Guided CPRF Procedures.

After patient preparation and sterilization, same in US Procedures. Under lateral FL (Siemens C-arm) guidance, direct the needle to the bone just below the sacral hiatus. Once you contact bone, then go superiorly to place the needle through anteroposterior fluoroscopic guidance the hiatus and into the sacral canal intervertebral level S2-3 [18-20].

2.3. After inserted RF

After inserted RF needle into caudal canal (see Fig.2), removed of it's stellite. Negative aspiration blood or cerebrospinal fluid. An electrode was connected to the cannula, and stimulation was conducted with impedance measured between 250 and 350 Ohms (Cosman G4 radiofrequency generator, Cosman Medical, Burlington, MA).

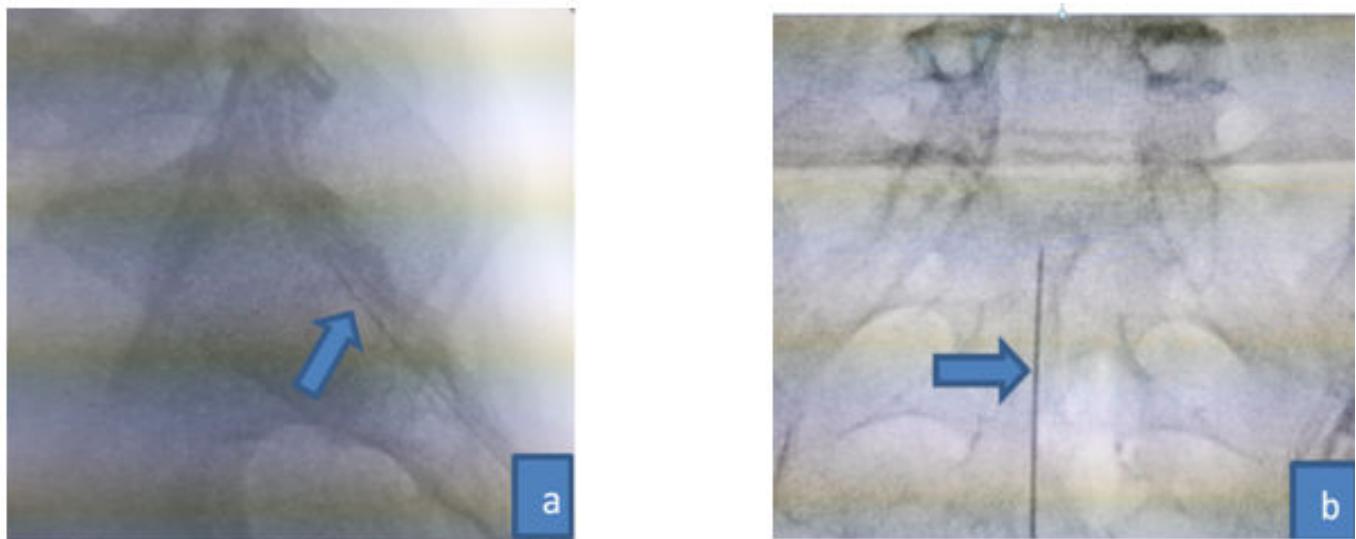


Figure 2. Fluoroscopy guide CPRF anterolateral (a) and lateral (b) Lumbosacral, Blue arrow RF needle.

The following procedures were used to conduct the teststimulation: Motor stimulation, produce perianal muscle contractions. Frequency, 2Hz, Pulse width; 1ms and Voltage; at least 1V. Sensory stimulation, produce paresthesia and numbness in perianal region. Frequency 50 Hz, Pulse width 1ms and Voltage up to 5V. Following the test, PRF was administered at 5 Hz for 600 seconds at 55 V with a 5-ms pulse width to keep the electrode tip temperature below 42°C.

2.4. Outcome Assessment.

The measurement of pain was evaluated by patients' ratings of a 10-point numerical painscale from 0 (no pain to) 10 (the worst pain). Pain was assessed before the procedure and follow up 4 hours after the procedure to detect any major complications. Revisit was evaluated in 2 days after treatment. All the patients were followed up at 30 days and 120 days intervals with telephone consultation and visits to the hospital.

2.5. Data Analysis.

The pain intensities were measured on a 0–10 NPS. The characteristics of the US and FL groups, such as sex, age, and duration of pain, were compared by the χ^2 test and Mann–Whitney *U* method. At each time point of the procedure, the NPS was compared by repeated measures analysis of variance, and the Bonferroni correction was conducted for post hoc comparison. Statistical analysis was carried out using SPSS 16.0 (SPSS Inc., Chicago, IL, USA). Values are expressed as means \pm SD and a *P* value of less than 0.05 was considered to be statistically significant.

3. RESULTS AND DISCUSSIONS

A total of 56 consecutive patients were assessed for eligibility during this study and completing the study. A flow diagram with patient selection and follow-up is presented in Figure 2. In US group, (n = 24 males and 32 females) completed. In FL group, two patients preferred US to avoid radiation exposure; a total of 26 patients (12 males and 14 females) completed this procedure. The patients had comparable pain duration for 21.3 ± 9.05 months as that of US group. The demographic data of patients are present in Table 1. The CPRF procedures were tolerable for all the patients during the treatment. However, 5 patients in US group and 4 patients in FL group felt dizzy immediately after injection; the symptom disappeared when they lay down on the bed for several minutes. All patients in both groups felt more comfortableness after the procedures. Mild analgesia give to the patients post the procedures with not more than 5 days. The mean NRS score for neuropathic pain in US group decreased from 6.8 ± 1.6 before CPRF done to 3.1 ± 1.8 after 2 days, 2.7 ± 1.3 after 30 days, and 2.4 ± 0.7 after 120 days after procedure.

The mean NRS score for neuropathic pain in FL group decreased from 6.7 ± 1.7 before CPRF done to 3.1 ± 1.6 after 2 days, 2.8 ± 1.4 after 30 days, and 2.5 ± 0.9 after 120 days after procedure.

There were no significant differences observed in the NPS before and 2wks, 12wks, and 24wks after the injections between US and FL groups (Table 1). The pain intensity, as measured by NPS, significantly decreased at 2days after the procedures in both US and FL groups, respectively, compared with that of baseline ($P < 0.05$). The comparable pain relieving effects appeared at 2 days, 30 days and 120days after treatment in both US and FL groups, the NPS score significantly decreased 2 days, 30 days and 120days after treatment compared with that at baseline ($P < 0.05$). It indicated that CPRF, guided by either ultrasound or fluoroscopy, had sustained pain-relieving effect for HSS patients.

Table 1. Comparison of the NRS Before and After Treatment.

	US	FL
Baseline	6.8 ± 1.6	6.7 ± 1.7
2 days	3.1 ± 1.8^a	3.1 ± 1.6^a
30 days	2.7 ± 1.3^a	2.8 ± 1.4^a
40 days	2.4 ± 0.7^a	2.5 ± 0.9^a

^a Significantly different from the baseline at $P < 0.05$.

HSS is a common clinical syndrome and few conservative managements lead to satisfactory clinical efficacy. There are still not determine causes of HSS Numerous prior researches on animal models of peripheral neuropathic pain have discovered activation of glial cells in the dorsal horn of the lumbar spinal cord[21-25].Glial cells emit pro-inflammatory cytokines when they are activated, which enhance pain signal transmission [26-28].After peripheral nerve damage, glial cells may be increased in DSP and generate cytokines that induce neuropathic pain. In the caudal area, the advantages of epidural PRF stimulation have yet to be shown. In a rat model of lumbar disc herniation, Cho et al. [29] found that caudal epidural PRF reduced dorsal horn nociceptive neuron activation at many levels of the lumbar spinal cord, as well as reducing microglial activity in the spinal dorsal horn from L3 to S1 [30-35]. S. Guven Kose et al. in a prospective CPRF study for thirty patients with failed back surgery had unsatisfactory responses to conventional treatments show pain relief in 36% with significant improvement in functionality, quality of life and opioid use [36].The only disadvantage of US guide not see the needle when entre caudal canal. This problem can resolve clinically. After the RF needle pass through the canal there are motor and sensory stimulation. The RF needle pass S23 if there are cerebrospinal fluid coming out from the needle during negative aspiration, foot contraction during motor stimulation or leg paresthesia in sensory stimulation. But when there are no perianal muscle contractions in motor stimulation or no paresthesia and numbness in perianal region in sensory stimulation, it mean the needle not reach S2-S3 either below S4 or not in caudal canal. For lateralization, there are obvious asymmetrical perianal contraction in motor stimulation or there are paresthesia in one side in sensory stimulation. It has also been reported that US-guided caudal injection for low back pain are feasible, easy to perform, and effective procedures. Ultrasonography may be a viable alternative to fluoroscopy or computed tomography as a guidance method because it overcomes the disadvantages of radiation exposure and poor vascular display. Furthermore, the device of ultrasonography is portable and convenient to be used at bedside for patients with severe pain [37-40]. The main limitations of the study are small number of patients, large sample required to confirm the procedure and this study was not a double-blind control study. Further investigations and tools may be needed to improve the limitations.

4. CONCLUSION

CPRF US-guided approach showed no significant effectiveness differences as compared with FL-guided block. Ultrasonography can be an alternative method for its convenience and efficacy in caudal approach without radiation exposure. Radiation safety is the biggest issue with the use of fluoroscope. On the other hand ultrasound is well established, and beyond doubts, it is one of the best diagnostic modalities. It has most available in outpatient clinic and it is promising in improving the results of spinal and peripheral nerve blocks. With the progress in research and improvement of ultrasound technology, there is a good chance that the ultrasound can gain more popularity as the imaging technique of choice for many chronic pain management procedures in future. More well-controlled studies are the need of the time before we recommend its use in routine clinical practice.

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