Randomized Controlled Trial

The Therapeutic Efficacy of Pulsed Radiofrequency Alone Versus a Dexamethasone and Pulsed Radiofrequency Combination in Patients With Trigeminal Postherpetic Neuralgia: A Double-blind, Randomized Controlled Trial

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Background: Pulsed radiofrequency (PRF) of the Gasserian ganglion is a common surgical intervention used to treat trigeminal postherpetic neuralgia (PHN). Dexamethasone has been reported to possess anti-inflammatory effects and potential analgesic benefits.

Objectives: The primary objective of our study was to compare the therapeutic efficacies of PRF alone versus a combination of PRF and dexamethasone for trigeminal PHN.

Study Design: A prospective, double-blind, randomized controlled trial.

Setting: Department of Pain Management, Wuhan First Hospital.

Methods: A total of 103 patients diagnosed with trigeminal PHN were randomly assigned into 2 groups (the PRF group and PRF plus dexamethasone [PRF+D] group). Digital subtraction angiography-guided puncture of the Gasserian ganglion was performed. All patients received PRF of the Gasserian ganglion first, and then a local injection was administered into the Gasserian ganglion. Patients in the PRF+D group received PRF therapy and one mL of 5 mg dexamethasone in the Gasserian ganglion, while patients in the PRF group received PRF therapy and one mL of normal saline in the Gasserian ganglion. The primary outcome was pain intensity, measured by the visual analog scale (VAS). The secondary outcome was quality of life, assessed by the Short Form-36 questionnaire (SF-36). The dosage of pregabalin administered was recorded to assess treatment effectiveness.

Results: Compared with the PRF group in this study, the PRF+D group showed more promising outcome results in pain relief as measured by the VAS; quality of life enhancement, as measured by the SF-36; and a reduced requirement for antiepileptic drugs ($P < 0.01$).

Limitations: Single center study, relatively small number of patients.

Conclusions: The therapeutic efficacy of PRF combined with a dexamethasone injection into the Gasserian ganglion was superior to that of PRF{and saline injection} alone of the Gasserian ganglion for trigeminal PHN.

Key words: Pulsed radiofrequency, trigeminal postherpetic neuralgia, dexamethasone, quality of life

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Herpes zoster is caused by the reactivation of latent varicella zoster virus (VZV) in the sensory ganglia, such as the dorsal root ganglion. Elderly and immunocompromised persons are prone to herpes zoster (1). The reactivated VZV can lead to a unilateral, painful vesicular rash confined to a dermatome. Postherpetic neuralgia (PHN) is conventionally defined as dermatomal pain persisting at least 90 days after the appearance of the acute herpes zoster rash, which is the most common chronic complication of herpes zoster (2,3). As VZV affects neurons of the trigeminal ganglion, it causes severe long-term neuralgia in the distribution(s) of one or more branches of the trigeminal nerve (4). PHN is characterized by persistent neuropathic pain that may continue long after the resolution of shingles (herpes zoster) (5). Trigeminal PHN is often severe and intractable and has a strong effect on quality of life.

Pulsed radiofrequency (PRF), a widespread treatment for chronic pain, is minimally invasive and causes few side effects associated with conventional radiofrequency, such as neuritis and deafferentation pain (6). Thus, PRF can be used for the treatment of neuropathic pain in patients who are refractory to conservative treatments (7). Previous studies have confirmed that PRF of the Gasserian ganglion can effectively relieve herpes zoster-related trigeminal neuralgia (8).

Glucocorticoids are a class of steroid hormones that possess important antiviral and anti-inflammatory properties. Dexamethasone, a high-potency, long-acting glucocorticoid, has been shown to attenuate tissue damage by inhibiting the inflammatory response in a variety of diseases (9,10). Notably, dexamethasone has also been shown to reduce systemic inflammatory response and provide pain relief under neuropathic pain conditions (11). Importantly, several studies have shown that dexamethasone can improve potency when applied perineurally in combination with local anesthetics (12). Additionally, dexamethasone has been found to relieve zoster-associated pain (13). To date, the therapeutic efficacy of a PRF plus dexamethasone (PRF+D) combination for trigeminal PHN has not been reported. Thus, the objective of this study was to investigate the therapeutic efficacy of PRF alone versus PRF+D into the Gasserian ganglion for patients with trigeminal PHN.

Methods

This study had a prospective, randomized, double-blind, controlled clinical design and was conducted from January 2018 through June 2020. The present study was approved by the ethics committee of the First Affiliated Hospital of Wuhan First Hospital, and informed consent forms were obtained from all patients.

In our study, patients who met the following criteria were included: 1) a diagnosis of classic PHN of the trigeminal nerve. Patients experienced lancinating or burning pain, paresthesia, or pruritus on areas innervated by the trigeminal nerve for over 3 months (14,15); 2) age > 60 years; and 3) a visual analog scale (VAS) score of 5 or above. Patients who met any of the following criteria were excluded from our study: 1) conditions were complicated by meningitis or myelitis; 2) coagulation disorders; 3) the use of an anticoagulant; 4) past invasive treatment; 5) cognitive impairment was too severe for them to provide information on the study instruments; and 6) topical and/ or systemic application of corticosteroids.

All patients were randomly assigned into one of 2 groups through a table of random numbers: the pulsed radiofrequency group (PRF group, n = 53), in which patients received a PRF of the Gasserian ganglion, followed by local saline injection (1 mL) into the Gasserian ganglion, and the PRF combined with dexamethasone group (PRF+D group, n = 53), in which patients received a PRF of the Gasserian ganglion followed by local dexamethasone injection (1 mL, 5 mg) into the Gasserian ganglion. After the different treatments, pregabalin was administered to all patients for pain relief according to changes in pain severity. Other treatments were avoided.

Outcome measurements

The primary outcome was pain relief. The degree of pain was assessed and monitored by VAS before treatment and 3 days, 7 days, 14 days, one month, 3 months, and 6 months after treatment. The secondary outcome was quality of life, which was assessed by the Short Form-36 questionnaire (SF-36) (16,17) before treatment and 7 days, one month, 3 months, and 6 months after treatment. The dosages of pregabalin (mg/d) were recorded at one day, 3 days, 7 days, 14 days, one month, and 6 months after treatment. Any adverse reactions, including serious bleeding, local infection, hematoma, intracranial hemorrhage, syncope, and serious pain, were also recorded at one day, 3 days, and 7 days after treatment in each group.

Intervention

Patients were supine and received oxygen

through a nasal tube at a flow rate of 3 L/min. Simultaneously, the heart rate, respiratory rate, oxygen saturation, electrocardiogram, and mean arterial pressure were routinely monitored. The route of percutaneous injection was performed under the guidance of digital subtraction angiography (DSA). A radiofrequency trocar (21G, 10 cm, 10 mm, Inomed,) was inserted and slowly advanced around the Gasserian ganglion using the Hartel anterior route. The C-arm of the DSA machine was adjusted to visualize the foramen ovale. The puncture point was selected 2.5 cm–3 cm outside the corner of the mouth on the affected side. After entering the skin, the radiofrequency needle direction was adjusted, and the needle was slowly advanced to the foramen ovale. We stopped advancing the needle when the needle tip had entered approximately 7 cm. Then, the needle tip was pierced into the foramen ovale to a depth of one cm, which was confirmed by lateral radiographs (Fig. 1A) and oblique radiographs (Fig. 1B). After that, a pulsed radiofrequency procedure (42°C, 2 Hz, 10 minutes) was conducted, based on previous studies (18). Then, the dexamethasone solution or normal saline was slowly injected around the ganglion. At the end of the operation, the puncture point was covered with a moulage compressive dressing and sterile gauze. Patients were monitored for at least 30 minutes before being sent back to the general wards.

Data Analysis

Quantitative data are presented as the mean ± SD values, while qualitative data are expressed using frequencies and percentages. Student t test or the Mann-Whitney U test was used to compare quantitative variables, as appropriate. The χ^2 test was used to compare percentages, including gender and the incidence of side effects. Rank sum tests were used to compare trigeminal neuropathy distribution. Statistical analysis was performed using SPSS 19.0 (IBM Corporation). A P value < 0.05 was considered to be statistically significant, while a value of $P < 0.001$ was considered to be highly statistically significant.

Results

Patient Demographics

A total of 485 patients were initially enrolled in the study from January 2018 through June 2020. However, 379 patients had to be excluded (24 patients did not meet the inclusion criteria, 319 patients received topical and/ or systemic application of corticosteroids, 16 patients declined to participate, 12 patients had been treated previously with PRF and 8 patients did not complete the follow-up evaluation). One patient in the PRF+D group and 2 patients in the PRF group were lost to follow-up. Finally, 106 patients met the study criteria and successfully completed the study after they

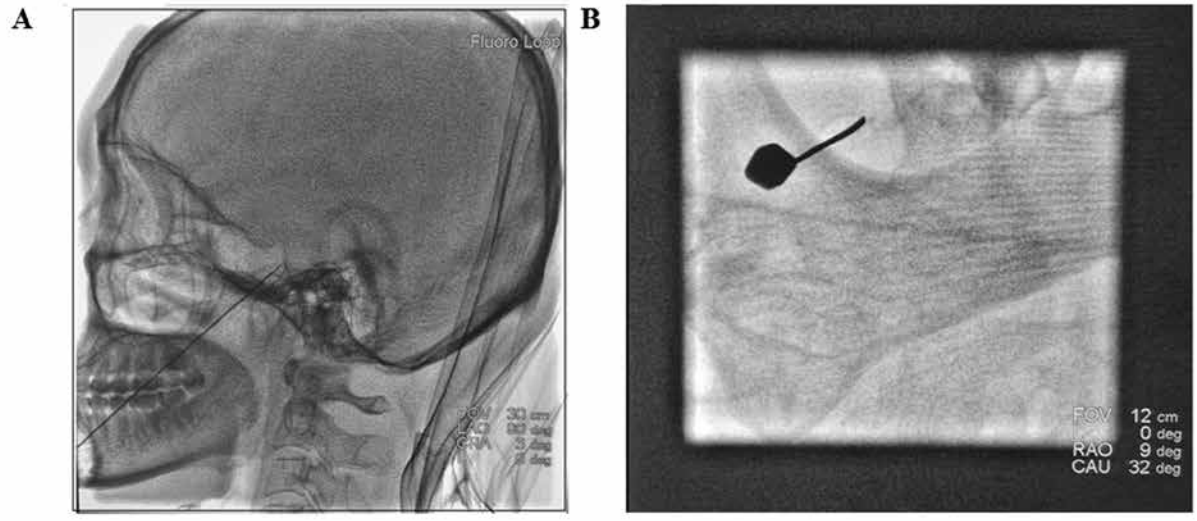

Fig. 1. *Digital subtraction angiography (DSA)-guided puncture of the Gasserian ganglion.* (A) *lateral radiographs* (Fig. 1A) *and* (B)*oblique radiographs.*

provided their consent. The flowchart detailing the follow-up procedure is displayed in Fig. 2.

No statistically significant difference was detected between groups regarding demographic characteristics, including mean age, weight, gender, pain severity, and trigeminal neuropathy distribution before treatment (Table 1), indicating that the preoperative characteristics were similar between groups.

VAS

The VAS score before the procedure did not differ between groups ($P > 0.05$). After treatment, patients in both groups had a significant reduction in VAS scores (Fig. 3). However, when compared with the PRF group, a statistically significant decrease in the posttreatment VAS scores at each time point was seen in the PRF+D group ($P < 0.001$).

SF-36

The baseline SF-36 scores before the procedure did not differ between groups. After treatment, both groups at different time points exhibited significant improvements in the index scores of general health, social function, emotional role, mental health index, bodily pain, physical function, and physical role ($P < 0.01$, Fig. 4). Interestingly, when compared with the PRF group, these index scores significantly increase at each time point after treatment in the PRF+D group ($P < 0.01$, Fig. 4).

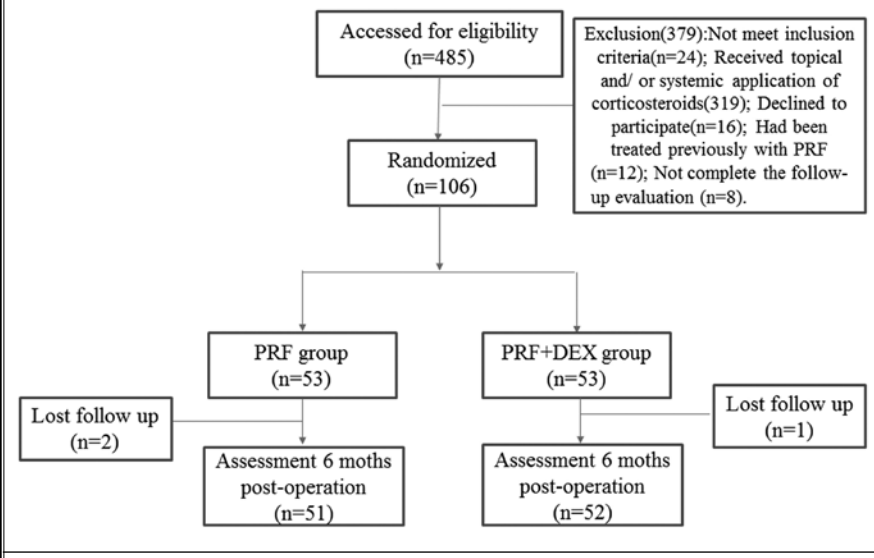

Fig. 2. *Study population and follow-up flowchart.*
Abbreviations: PRF, pulsed radiofrequency; D, dexamethasone.

Rescue Drug Dosage

The dosage of pregabalin administered per day was lower in the PRF+D group than in the PRF group at each time point ($P < 0.01$, Fig. 5).

Side Effects

None of the 106 patients in either group developed severe complications, such as cerebrospinal fluid leakage, intracranial hemorrhage, diplopia, chewing weakness, or auditory disorder. The adverse events included pain at the injection site, bleeding, bradycardia, tachycardia, and high blood pressure. All symptoms rapidly recovered after symptomatic treatment.

Table 1. *Demographic characteristics.*

Variables	PRF group (n = 51)	PRF+D group (n = 52)	*P*
Age, years	63.47 ± 13.24	62.85 ± 14.52	0.822
Gender (Women/Men)	28/25	26/27	0.698
Weight (kg)	68.36 ± 10.13	67.64 ± 11.34	0.735
Average pain scores	7.21 + 0.78	7.45 ± 0.81	0.129
Trigeminal distribution (I/II/III branch)	8/17/28	10/16/27	0.744

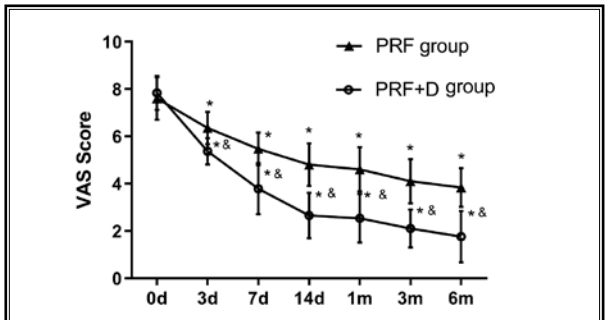

Fig. 3. *Change in visual analog scale (VAS) scores.*
*$P < 0.01$ indicates pretreatment versus posttreatment. #$P < 0.01$ indicates PRF+D group versus PRF group.

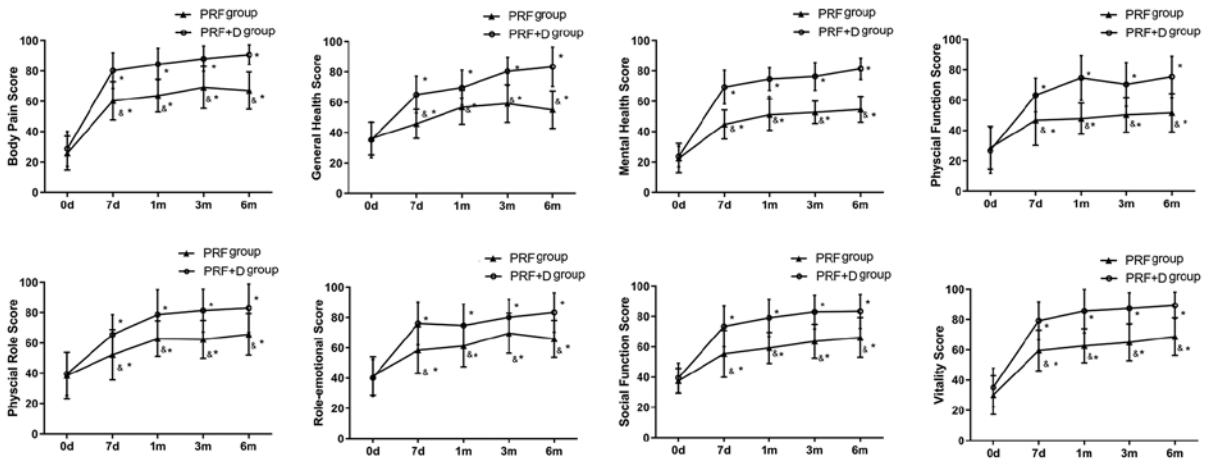

Fig. 4. *Change in SF-36 scores*.
*$P < 0.01$ indicates pretreatment versus posttreatment. #$P < 0.01$ indicates PRF+D group versus PRF group.

Discussion

To the best of our knowledge, our study is the first to compare the effectiveness of PRF alone and PRF followed by dexamethasone injection into the Gasserian ganglion for trigeminal PHN. Our results demonstrated that PRF followed by dexamethasone injection into the Gasserian ganglion conferred significant pain relief, a reduced requirement for antiepileptic drugs, and an improvement in quality of life compared with the injection of PRF alone into the Gasserian ganglion.

The reactivation of VZV in neural cells produces a new wave of viral replication within the dorsal root ganglia, which contributes to central and peripheral nerve damage (19). Excessive abnormal electrical impulses are the result of impaired sensory neurons and are transmitted to the spinal cord, inducing spontaneous pain (20). Additionally, it has also been suggested that VZV infection results in an enhanced inflammatory response that in turn promotes neural damage and exaggerates neuralgic pain (21). As a confluence of all 3 trigeminal branches, the Gasserian ganglion is the primary target of VZVs in zoster-related trigeminal neuralgia (22). Thus, we selected the Gasserian ganglion as the therapeutic site.

The use of high frequency current at 500 kHz, called radiofrequency, is well introduced in pain management (23). Until the present, there were multiple different types of radiofrequency procedures, including radiofrequency ablation (RFA) and PRF. RFA is performed by the delivery of electrical energy through a needle electrode to the area of interest, using high-frequency electrical current in order to cause heat-based nervous tissue damage. This disruption results in the ceasing of upward transmission of pain signals to produce a reliable analgesic effect (24). In contrast to RFA, PRF applies a brief electrical stimulation, followed by a long resting phase. Thus, PRF does not produce sufficient heat to cause structural damage. PRF has an unclear analgesia mechanism. Currently, PRF is thought to relieve pain through the altering of physical characteristics of neuronal cell membranes (25). Because of its high safety and few side effects, PRF has been growing in popularity. Interestingly, a recent study has confirmed that PRF to the Gasserian ganglion is an effective and safe therapeutic option for patients with zoster-related trigeminal neuralgia (18).

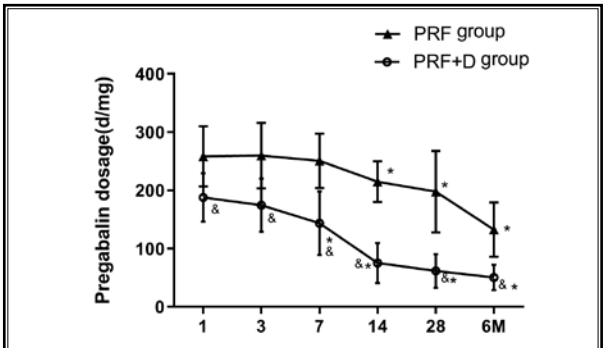

Fig. 5. *Change in dosages of pregabalin*.
*$P < 0.01$ indicates pretreatment versus posttreatment. #$P < 0.01$ indicates PRF+D group versus PRF group.

As a local anesthetic adjunct, dexamethasone enhances the analgesic effects of different local anesthetics. For example, perineural dexamethasone (5 mg) provides a longer duration of postoperative analgesia for nerve block (26). Typically, steroids are used after RFA to reduce postprocedure neuritis. Recently, a few studies have demonstrated that adding steroids benefits patients with PRF. For example, Li et al (27) found that PRF combined with steroid injections can provide sustained pain relief and improve the quality of life for patients with cervicogenic headache. Fam et al (28) found PRF and steroid injection to be an effective and safe method for postmastectomy pain syndrome.

The SF-36 is a general health survey that is widely used in the assessment of quality of life in patients with chronic pain (29). Our findings indicate a significant improvement in pain intensity and quality of life after treatment with only PRF of the Gasserian ganglion or PRF followed by local dexamethasone injection into the Gasserian ganglion. Furthermore, the improvement in the combination treatment was more apparent than that in the PRF group at each time point, and the differences were statistically significant. The dosage of pregabalin administered was significantly lower in the PRF+D group than in the PRF group at each time point after treatment. Thus, these results suggest that local dexamethasone injection into the Gasserian ganglion enhanced the treatment outcomes of PRF of the Gasserian ganglion in patients with trigeminal PHN.

Several potential mechanisms can drive these treatment effects of dexamethasone. First, trigeminal postherpetic neuralgia is related to the varicella zoster virus. Dexamethasone, a steroid with known immunoregulatory capacities, suppresses the immune response system of the host to respond against the virus. Second, steroids are the most common and effective anti-inflammatory drugs (30). Topical application of dexamethasone may attenuate oxidative stress, proinflammatory factor production, and inflammatory cell infiltration associated with VZV infection. Thirdly, PRF also results in less severe nerve injury, which is partially alleviated by dexamethasone. Fourth, dexamethasone appears to have some analgesic effects. Previous studies in patients undergoing dental procedures have shown that glucocorticoids were effective in relieving postoperative pain (31,32). Recently, a study has confirmed the potential analgesic benefit of a single perioperative dose of dexamethasone (33).

Limitations

There are a number of limitations associated with the present study. First, all 106 cases were from the same center, and there were a relatively small number of patients. A multicenter study with a larger sample needs to be carried out in the future. Secondly, a large number of cases of PHN in the ophthalmic division were excluded. The ophthalmic division is the most affected trigeminal nerve (34). Common ocular complications in herpes zoster ophthalmicus include keratitis, iridocyclitis, and conjunctivitis. Typically, the therapy for herpes zoster ophthalmicus includes topical and/or systemic application of corticosteroids (35). Additionally, the ophthalmic nerve root is located deep in the Gasserian ganglion, resulting in a difficult puncture, high risk, and difficulty in reaching the target (36). Therefore, a few patients with PHN in the ophthalmic division were excluded for this reason. Furthermore, the present study examined the effectiveness and safety no longer than 6 months after treatment. However, longer follow-up periods would confirm the results or elicit more or less favorable results over time. Finally, the present study did not compare different doses of dexamethasone administration. Future dose-finding studies are required to elucidate the optimal dose of dexamethasone.

Conclusions

In summary, our results demonstrated that PRF followed by local dexamethasone injection into the Gasserian ganglion conferred significant pain relief, a reduced requirement for antiepileptic drugs, and an improvement in quality of life compared with only PRF of the Gasserian ganglion.

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